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# Identifying risk and protective factors in conditional release/discharge using systematic review and exploring lived experiences of compulsion and restriction orders using interpretative phenomenological analysis: A portfolio thesis in forensic mental health.

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*Out beyond ideas of wrongdoing and rightdoing, there is a field. I'll meet you there.* ~ Rumi

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## Thesis portfolio abstract

Compulsory treatment presents an ethical quandary and thus far research provides little promise regarding reduced readmission or length of inpatient stays, though some value has been shown in administering outpatient treatment. Those in forensic services and particularly those under restriction orders face the greatest constraints on their liberty with detention imposed “without limit of time”, unlike time-limited sentences in the prison system. There is a dearth of research exploring patients perspectives of compulsory treatment and particularly the most restrictive forms of this. The current study used interpretative phenomenological analysis to analyse interviews with participants about their experiences of living under restriction. Results derived four superordinate themes; (1) *How did I end up here?* (2) *Impact: Power, Punishment and Protection* (3) *Surviving and Adapting* (4) *Healing*. The results are reviewed in the context of extant findings; clinical implications and areas of future research are discussed.

Conditional release (CR) is the primary mechanism for managing individuals under forensic care in the community. Services must identify those at higher risk for revocation/ readmission (RR) and promote protective factors for increased quality of life and to minimize recidivism. A systematic search was conducted to identify, summarise and critically assess studies that have evaluated factors associated with RR in forensic patients. The review found that higher substance use, personality disorder/ traits, severity and chronicity in psychiatric illness, criminality and minority ethnicity are risk factors for RR. Protective factors identified were: white ethnicity, being married, social security, not having personality disorder, longer tenure in outpatient programme, clozapine treatment, fewer incidents while on CR, labour skills and higher functioning at CR. Future research should include prospective study designs, standardised measures, and variables independent from RR. Clinical implications include identification of individuals with risk factors for RR and promotion of protective factors.

## Thesis portfolio lay summary

When individuals are very mentally unwell, they may need to be placed under a legal order which means they are required to participate in some forms of care and treatment. For example, take prescribed medication and be admitted to hospital until such time as their care team agrees it is safe for them to return to their own home. This is known as compulsory treatment. Compulsory treatment presents an ethical dilemma because it means that a persons freedoms are restricted and they may be under the legal order for a long time, potentially indefinitely. So far research has shown that these legal orders may not reduce hospital admission frequency or length. Though some value has been shown for compulsory treatment in the community as it means there may be more treatments available in the community. People looked after by forensic mental health services (FMHS) and particularly those under “compulsion order/ restriction order” (CORO) face limits on their freedoms and being in hospital or in the community under supervision for an indefinite time, unlike time-limited sentences in the prison system. There is little research exploring patients views of compulsory treatment and particularly the most limiting forms of this. This study used interpretative phenomenological analysis (a way of looking for meaning and common patterns across individuals views) to analyse interviews with people about their experiences of living under restriction orders. The study showed that there were 4 main patterns in peoples experiences. The first pattern showed that people attempt to make links between their offending and mental illness and why they came to be looked after by FMHS. Some noted they were not sure what CORO was to start with and only realised the seriousness of this later. The second pattern showed the impact being on CORO had on people. Some people found being on CORO comforting as it made them feel safe to know they had staff looking after them and medicines and other treatments available to keep well. Others felt like they were being punished for having a mental illness, felt under constant watch, and that other people made important choices for them and decided what direction their life was going in. The third pattern found that people developed different ways of coping with the unusual situation they were in. Some people accepted the care and treatment and were happy to do this, some people accepted it in their actions (e.g. they took medicine) but did not agree with it. Some people attempted to get a feeling of power or choice by challenging their CORO at tribunals, writing advanced statements, or challenging rules on the ward. The final pattern showed that people found a variety of things helpful in getting better such as: the right medicine (although this was a journey and took time), therapeutic activities, treating staff well and being treated well in return, and finding the best way to tell new people in their lives about their mental illness and offending. The results are looked at in the context of research that came before it and what this means for people living under CORO and for mental health services is considered.

Conditional release (CR) is the main method for managing individuals under forensic care in the community. Services must identify those at higher risk of returning to hospital (and being enforced to return legally (RR)) in order to boost protective factors for increased quality of life and to reduce reoffending. A structured search of all the research that would answer this question was done. This research was assessed for quality and to determine what it found. This study found that higher substance use, personality disorder/ traits, having a more severe psychiatric illness and for longer, criminality, and minority ethnicity are risk factors for RR. Protective factors identified were: white ethnicity, being married, social security, not having personality disorder, longer time in outpatient care, clozapine treatment, having fewer incidents while on CR, having labour skills, and higher functioning at CR. These findings were then discussed in relation to the existing wider research findings, how future research could be improved, and what this means for clinicians working with patients.

**Journal Article 1: Systematic Review**

# Risk and protective factors for revocation & readmission in forensic conditional release/discharge: A Systematic Review

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## Abstract

Conditional release (CR) is the primary mechanism for managing individuals under forensic care in the community. Services must identify those at higher risk for revocation/ readmission (RR) and promote protective factors for increased quality of life and to minimize recidivism. A systematic search was conducted to identify, summarise and critically assess studies that have evaluated factors associated with RR in forensic patients. The review found that higher substance use, personality disorder/ traits, severity and chronicity in psychiatric illness, criminality and minority ethnicity are risk factors for RR. Protective factors identified were: white ethnicity, being married, social security, not having personality disorder, longer tenure in outpatient programme, clozapine treatment, fewer incidents while on CR, labour skills and higher functioning at CR. Future research should include prospective study designs, standardised measures, and variables independent from RR. Clinical implications include identification of individuals with risk factors for RR and promotion of protective factors.

# Introduction

## Conditional release/discharge and readmission

Forensic patients who progress through secure care and are evaluated as safe to live in the community are “conditionally released/ discharged” (CR/CD) through mental health tribunals, review boards or similar depending on the jurisdiction under which they live (Marshall et al., 2014). Access to the community is regulated as there are mandatory conditions and restrictions to comply with. For example, housing arrangements, medication compliance, drug and alcohol screening, and attending appointments with clinical services. Breaching these conditions or engaging in offending behaviour can lead to revocation of CR and return to secure forensic hospital (RR) (McDermott & Thompson, 2006; McGreevy et al., 1991; Segal & Burgess, 2006). Revocation rates appear to have fallen somewhat over time (see Table 2) and in the most recent studies generally sit between 25-45% of any given sample. Studies tend to demonstrate that revocation occurs largely for reasons of decompensating mental health or rule violation rather than commission of new offences (see Table 1 for summary examples of reasons for RR). As this population typically presents with severe and enduring mental illness, deterioration in mental state is expected episodically to some extent. Therefore, psychiatric readmissions have been considered essential elements of long-term management (Heilbrun & Griffin, 1998; Kravitz & Kelly, 1999). The management of these individuals in the community has been investigated using two main outcome variables; criminal recidivism and RR (Marshall et al., 2014).

Revocation has often become interchangeable with rehospitalisation (also commonly known as recall and readmission) (Marshall et al., 2014). The act of being psychiatrically readmitted may lead to revocation; thus, rehospitalisation can be considered a proxy for CR revocation. However, readmission does not necessarily lead to revocation. It is difficult to differentiate between these outcomes as they are often synonymous or not clearly defined or differentiated in studies. Both outcomes are arguably strongly linked.

Some studies report reasons for revocation (i.e. reasons identified for an individual being revoked rather than predictors of revocation itself) and these are often overlapping or involve a series of events (Table 1). For example, breaching more than one of a list of conditions (Hayes et al., 2014). The literature does not consistently report reasons for revocation or provide clear distinction or study designs which would allow for discrimination between factors which are associated with revocation for criminal vs clinical reasons (Marshall et al., 2014). Some studies and jurisdictions include relapses of mental illness as reason for revocation (Bloom et al., 1986; Callahan & Silver, 1998; Manguno-Mire et al., 2014; Vitacco et al., 2018) and others manage relapses of mental illness by admission to hospital without revocation of

CR (Hayes et al., 2014; Vitacco et al., 2008; 2011). Thus, the literature demonstrates varying methods of measuring variables which are difficult to compare. Small sample sizes and large overlap in reasons for instigating revocation have been cited as prohibitive factors in the examination of differences in factors associated with or predictors of criminal vs clinical revocation/recall (Jewell et al., 2018).

## Maintaining conditional release

Historically, the literature regarding “not guilty by reason of insanity acquittees” has found that static variables, such as criminal history and demographics tend to be more consistently related to maintenance of CR than dynamic clinical and aftercare factors (Monson et al., 2001). Variables such as Caucasian ethnicity, being employed, and married were significantly associated with maintaining CR (Callahan & Silver, 1998; Tellefsen et al., 1992). Those who have a history of previous criminal offending were more likely to have their CR revoked than those for whom the index offence was their first offence (Callahan & Silver, 1998). One study found that the non-revoked group had significantly longer tenure in outpatient programs, more frequent diagnosis of mental retardation, fewer previous psychiatric admissions, less frequent diagnosis of schizophrenia, fewer incidents, and fewer prior arrests overall than those in the revoked group (Bertman-Pate et al., 2004). Suggesting those who are able to maintain CR successfully experience better mental health and are less antisocial. However, the literature presents conflictual findings as one study demonstrated that a diagnosis of paranoid schizophrenia was a significant predictive protective factor in the outcome of hospitalisation and/or arrest (Parker, 2004). These factors may be influenced by inter-jurisdiction differences in thresholds for psychiatric admission. With some services/ areas viewing rehospitalisation as a positive step in the prevention of further violence and not only as an outcome measure to indicate treatment failure (Kravitz & Kelly, 1999). Thus, these services likely have more flexible readmission thresholds and higher rates or readmission. Indeed, an early literature review of community treatment and CR in the USA found that states with higher rates of rehospitalization were associated with lower rates of re-arrest (Heilbrun & Griffin, 1993). In addition, supportive housing compared to independent housing, having an older age at index verdict and being female have been demonstrated to be associated with lower risk of readmission while on CR (Salem et al., 2015).

**Table 1.**

*Summary examples of reasons for revocation and return to hospital*

| Study First Author (Year) | Reason for Revocation/ Return to hospital [a] (%) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Bloom (1986)** | **Callahan (1998)** | **Hayes (2014)** | **Jewell (2018)[a]** | **Manguno-Mire (2014)** | **Melnychuk (2009)[a]** | **Norko (2016)** | **Novosad (2016)** | **Penney (2018) [a]** | **Vitacco (2011)** | **Vitacco (2018)** |
| **Decompensating mental health** | 74 | 60%$^{C}$ > 70%$^{M}$ > 20%$^{NY}$ > 40%$^{O}$ | | 86 | | 59.7 | 26.4 | 54 | 46 | | 50.6 |
| **Non-compliance with CR supervision/ missing outpatient appointments/ Absconding from supervision/ Breach conditions/ Violation of a general rule** | 74 | | | | 91.4 | 26.8 | 15.1 | 27 | 8 | 75 | 12.3 |
| **Non-compliance with treatment** | 65 | | 29.1 | | | | 13.2 | | 25 | | |
| **Non-compliance with medication** | 24 | | 23 | 56 | | | 3.8 | | | | |
| **Substance Use (incl. alcohol)** | 24 | ~15%$^{C}$ > 20%$^{M}$ ~5%$^{NY}$ > 10%$^{O}$ | 68.8 | 56 | | 59.9 | 22.6 | | 46 | | |
| **Elopement/ absconding/ absent from accommodation without leave/ Away without leave (AWOL)** | 39 | | | 16.7 | | | 1.9 | | 13 | | 34.6 |
| **Commission of a new crime (incl. non-violent)** | 24 | | | | | | | | | | 1.23 |
| **Displaying troublesome/ threatening behaviour/ Risk/ Dangerousness** | 59 | 80%$^{C}$ > 25%$^{M}$ > 80%$^{NY}$ > 60%$^{O}$ | | 51 | | | 1.9 | | 13 | | |
| **Violence** | | | | 23 | 5.2 | 35.4 | | | | | |
| **Act or threat of violence** | | | 58.3 | | | | | | | | |
| **Sexual Assault** | | | | | | | 1.9 | | | | |
| **Inappropriate sexual behaviour** | | | | | | | 1.9 | | | | |
| **Needing to complete a prison sentence** | | | | | | | | | | | 1.23 |
| **New Charges** | | | | | | 59 | | | | | |
| **Nonviolent criminal activity** | | | | | 3.4 | | 1.9 | | | 25 | |
| **Loss of program** | | | | | | | 3.8 | | | | |
| **Arrest** | | | | | | | 1.9 | | | | |
| **Inappropriate phone calls** | | | | | | | 1.9 | | | | |
| **Needs higher level of service** | | | | | | | 1.9 | | | | |
| **Inadequate supervision and treatment** | | | | | | | 1.9 | | | | |
| **Other (incl. actual conviction)** | 4 | | | 1 | | 7.6 | | | | | |

N.B. All papers included in this systematic review who reported reasons for revocation (7/18) are reported above in addition to some other relevant studies who reported this information but are not included in the systematic review as they did not meet criteria for inclusion. Figures have been rounded up to 1 decimal place and some studies reported multiple reasons for 1 failure of CR so totals may equal > 100%. [C]Connecticut; [M]Maryland; [NY]New York; [O]Ohio

## Rationale

CR is the primary mechanism for managing individuals under the care of forensic mental health (FMH) services who are discharged to the community. This involves close monitoring of these individuals and is resource intensive. Nonetheless, CR is an attractive alternative to long-term inpatient treatment which can be overly restrictive and limit quality of life for the many individuals who no longer require secure care but face little alternative if community services are inadequately developed. It is important for services to focus resources to promote protective factors and to mitigate risk factors in order to minimize recidivism and increase quality of life.

There has been very limited appraisal of this area of the literature in general and the evaluations that have taken place are outdated or very limited in scope (Adjorlolo et al., 2019; Heilbrun & Griffin, 1993). Many factors in the care and treatment of this population have changed significantly over the past 30 years, not least advances in antipsychotic medication such as clozapine (Kane et al., 1988; Tiihonen et al., 2011), psychological interventions for psychosis (Burns et al., 2014) and emotion and relational dysregulation (Blum et al., 2008; Bateman & Fonagy, 2004; Linehan, 1993; Young et al., 2003). The most recent review was limited in that it included only 3 papers which appear to be from the same research team (namely, Vitacco et al., 2008, 2011, 2014), had no risk of bias assessment, reviewed papers between 2004-2019 only, and only included participants under the “insanity defense” label rather than the wider FMH population under CR (Adjorlolo et al., 2019). It concluded that being grouped into high risk supervision group, history of prior revocation, substance use, and breaches of release rules appeared to consistently predict revocations. The current review will aim to provide a more comprehensive synthesis of a larger sample of papers over a longer time period in order to identify the veracity of those findings and assess the quality of the available literature.

In conclusion, a broad range of variables appear to be related to the failure and maintenance of CR in FMH patients. This topic has not been comprehensively systematically reviewed before to the knowledge of the authors. The outcome of this systematic synthesis of the literature aims to identify protective and risk factors for RR in order to inform treatment targets, promote successful maintenance in the community, minimise recidivism, and increase quality of life.

## Aims

The current systematic review intends to systematically identify, summarise and critically assess studies that have evaluated factors associated with RR in forensic patients. The review seeks to address the following research questions:

- What factors are found to be associated with revocation?
- What factors are found to be associated with return to hospital?
- What factors are found to be associated with successful maintenance of conditional release/discharge?
- What are the methodological sources of bias in the literature?
- Provide an overview of the studies in this area.

Recidivism is also commonly used as an outcome variable in studies evaluating the outcomes of CR'd patients however this is beyond the scope of the current review. This review aims to investigate factors associated with RR specifically.

# Methods

## Design

A systematic review was conducted in line with the PRISMA Guidelines (Appendix 2).

## Inclusion and exclusion criteria

An article was included if:

- The full sample comprised of participants who were defined as:
    - Patients cared for by FMH services.
    - Who were living under CR/CD in the community.
- The study performed a statistical measure of association between:
    - Characteristics of the participants.
    - Outcomes defined as at least one of the following:
        - Revocation or a clear proxy.
        - Readmission or a clear proxy.

An article was excluded if it was:

- Non-English language papers.
- Unpublished literature.
- Qualitative studies.

- Single case studies.
- Conference abstracts.
- Book chapters.
- Review articles not using original data (e.g. editorials, commentaries, meta-analyses).
- Studies whose full text was not available.

## Search strategy

On 29th January 2020, electronic databases were searched (from their inception date onwards) for relevant articles in accordance with the inclusion and exclusion criteria detailed above. The following databases were searched: Embase (1974 – search date); PsychInfo (1980 – search date), CINAHL (2003 – search date), and OVID-Medline (1946 – search date).The 3 sets of subject headings and free-text terms below were combined with the Boolean operator “AND” in each database:

- Forensic OR Forensic Psychology (MeSH) OR Forensic Psychiatry (MeSH) OR Incarceration (MeSH) OR incarcerated OR Mentally Ill Offenders (MeSH) OR insanity* acquittee* OR Mental Disease (MeSH) OR Mental* Ill* OR NGRI aquittee* OR Insanity OR Mental Disorders (MeSH) OR Psychiatric* OR Forensic Mental Health OR Forensic Psychiatric Patient* OR Forensic Patient* OR NGRI OR Mentally Disordered Offender
- Conditional* discharge* OR Conditional* Release* OR Community Treatment Order
- Revocation OR Licence Revocation (MeSH) OR Revoke* OR Psychiatric Hospital Readmission (MeSH) OR Rehospitalization OR Recall* OR Psychiatric Hospitalization (MeSH) OR Hospitalization

Any duplicate articles were removed. Then the lead author examined all titles and abstracts for eligibility based on the inclusion/exclusion criteria. Where it was unclear whether inclusion criteria were met, the full paper was obtained. Reference lists of included studies were searched and this generated one additional paper for inclusion in this review. Therefore, verifying the comprehensiveness of the search strategy as only one novel paper was identified in this way. See Figure 1 for an illustration of the search procedure.

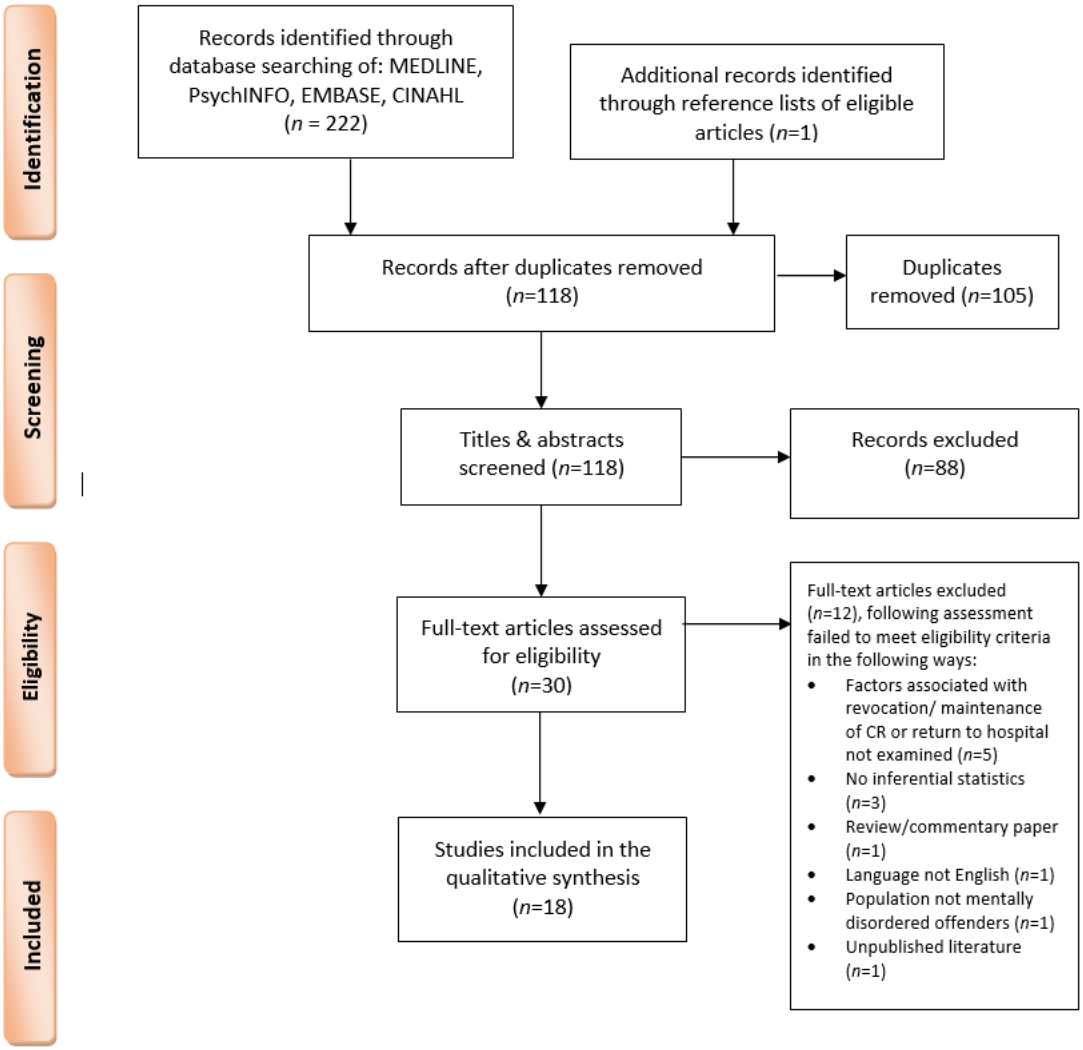


*Figure 1.* Prisma Flow Diagram

The search strategy generated 222 records. Titles and abstracts were initially screened, and 30 full-text articles assessed. The final sample totalled 18 original research articles that met eligibility criteria.

## Quality assessment and risk of bias

An assessment of quality and risk of bias was undertaken using an adapted version of the Appraisal tool for Cross-Sectional Studies (AXIS) tool (Downes, Brennan, Williams, & Dean, 2016). The tool was adapted to tailor this more closely to identify issues commonly found in the pseudoprospective research in this area. This included addition of criteria regarding adequate follow-up period in order to allow for the "event" (dependent variable i.e. RR to occur), the reporting of effect sizes to identify whether clinically relevant effects are found and to facilitate comparison between studies, and finally, whether confounding variables were identified and strategies developed to manage the multiple variables and statistical tests undertaken. Following several pilots and revisions, the final version comprised twenty-two

quality criteria (Appendix 4). The lead author examined the quality and risk of bias of all included studies, and an independent reviewer repeated this assessment procedure for nine out of 18 studies (50%). Initially, 175 of the 198 ratings (88.4%) across the 9 papers achieved agreement between both reviewers. All 23 rating discrepancies were only one category apart (i.e. “well covered” vs. “adequately covered”). One hundred per cent consensus was reached on all ratings when discussed between reviewers.

Follow-up period was considered well covered if it exceeded two years or more. The rationale for this was due to studies typically demonstrating that the average length of time in the community prior to revocation was approximately this length time or less. For example, across four states in the USA the median length of time was found to be 1.7 years (range 1.0-3.0 years) (Callahan & Silver, 1998). An Australian study found that half of all revocations occurred within the first 12 months after granting of CR and the majority occurred within the first two years after CR (Hayes et al., 2014). Thus, it was considered that problems typically arise within the first two years of CR.

A power analysis estimate (taking into account previous studies investigating variables of interest) calculated that 125-128 cases would surpass the minimum requirements and sit within the range of suggested participants (Monson et al., 2001). This was used as the rater’s criterion for adequate sample size for the risk of bias assessment.

## Results

### Study selection and characteristics

The final sample comprised 18 original research articles that met eligibility criteria. See Table 2 for full description of study characteristics. One study included was a female sub-sample (Vitacco et al., 2011) with longer follow-up (*M* = 2.85 vs. *M* = 4.6 years) derived from another included article (Vitacco et al., 2008). In another case, two articles sampled from the same aftercare clinic but sampled data at different time periods; it is likely that some but not all participants are present in both samples (Bertman-Pate et al., 2004; Manguno-Mire et al., 2014). It was not possible to differentiate those cases appearing in both and the decision was made to include all. The 2014 article expanded on the variables included in the 2004 paper and added selected risk variables identified in the literature and performed logistic regression analysis in addition to the original bivariate analysis.

The final pool of studies included 16 fully discrete cohorts, described in 18 articles, providing a total sample size of *n*=3872 participants (although there may be some overlap between two sets of studies (Bertman-Pate et al., 2004; Manguno-Mire et al., 2014; Vitacco et al., 2008,

2011)). Males ranged between 74-84.4% of samples included in all but one paper which was exclusively female (Vitacco et al., 2011). The mean age of participants was 42.8 years, however four studies did not provide a mean age for participants included in analysis for factors relevant to this review (Bloom et al., 1986; Callahan & Silver, 1998; Stoner et al., 2002; Tellefsen et al., 1992). Sample size ranged from *n*=25 (Stoner et al., 2002) to *n*=837 (Salem et al., 2015). Article publication dates range from 1986 (Bloom et al., 1986) to 2018 (Jewell et al., 2018; Vitacco et al., 2018).

Fourteen samples were recruited from USA; two from UK; and one each from Australia and Canada. All studies were cross-sectional and/or pseudo prospective in design. Samples were recruited from forensic hospitals or aftercare programs.

## Representativeness and generalizability of studies

The majority of papers were adequately representative of the FMH population released on CR/CD. Studies included mainly male patients, main primary diagnoses of a psychotic illness, and mean age between 30-50 years old. All but three studies included participants of both genders; two studies did not report gender (Callahan & Silver, 1992; Tellefsen et al., 1992) and one had a wholly female sample (Vitacco et al., 2011).

Diagnoses of schizophrenia/psychotic spectrum disorders ranged from 44.7% (Vitacco et al., 2011) to 89.1% (Jewell et al., 2018). Substance use/abuse diagnoses or “problems” ranged from 15% (Bloom et al., 1986) to 73.6% (Jewell et al., 2018). More recent studies tended to report higher rates of substance use. Personality disorder (PD) diagnosis ranged from 7.9% (Vitacco et al., 2014) to 39.5% (Vitacco et al., 2011). Specifically, antisocial PD (ASPD) ranged from 7.9% (Vitacco et al., 2011) to 22.5% when traits of ASPD were included (Marshall et al., 2014) and 26.4% when all “Cluster B” personality diagnoses were recorded (Monson et al., 2001). Intellectual disability was not reported in most studies but ranged from 7.1% for borderline/mild ID (Hayes et al., 2014) to 42.5% (Manguno-Mire et al., 2014) where noted.

The majority of papers considered all ages from 16-18 years onwards and the resultant age range in papers included was 16-84 years old. The variation in mean age across papers was 35-46.9 years old. Notably, studies varied in which time point they measured age (e.g. at time of index offence, at time of release to CR, at time of study data collection).

The majority of the datasets were from forensic psychiatric hospitals or aftercare programs. As 77.8% (14/18) of studies and 68.4% of participants were from USA the study selection sample will likely be more generalisable of this population.

Fourteen papers utilised multivariate analytical methods i.e. association between independent variables and revocation/return to hospital was assessed controlling for confounders (though variables controlled for were very varied and often not stated). Four studies used bivariate analyses only (Bloom et al., 1986; Bertman-Pate et al., 2004; Stoner et al., 2002; Wiederanders et al., 1994).

Seven papers did not report the ethnicity of participants (Callahan & Silver, 1998; Hayes et al., 2014; Parker, 2004; Riordan et al., 2006; Salem et al., 2015; Stoner et al., 2002; Tellefsen et al., 1992). Seven papers reported a majority Caucasian sample (Bloom et al., 1986; Monson et al., 2001; Vitacco et al., 2008; 2011; 2014; 2018; Wiederanders et al., 1994). Four papers reported a largely ethnicity minority sample (Bertman-Pate et al., 2004; Jewell et al., 2018; Manguno-Mire et al., 2014; Marshall et al., 2014).

**Table 2.**

*Study characteristics*

| First Author, Year State if given, Country | Sample size (*n*), Population | Males (%) | Age in years (M, SD, Median and/or Range) | Ethnicity (White) (%) | Diagnosis (%) | Relevant study aims | Study design/ analysis | Follow-up period/ Average length of CR/ Years of study | Source of data/ data collection method | Effect size reported | Revoked/ Readmitted[x] rate (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Bertman-Pate, 2004**<br><br>**Louisiana, USA** | 119 NGRI | 81.5 | 38[d] | 18.5 | 40.3=Schizophrenia<br>37=DSM-IV diagnosis of mental retardation,<br>68.9=Substance abuse or dependence<br>23.5=PD | Presentation of data on revocation of CR | Pseudo-prospective<br><br>Kruksall-Wallis | Mean tenure in program was 22.6months<br><br>Clients attending clinic 1995–2002 | Not stated | - | 34.5 |
| **Bloom, 1986**<br><br>**Oregon, USA** | 67 IAs | - | - | 73.3 | 53=Schizophrenia<br>15=Substance abuse | To describe those treated by outpatient treatment program (remained in program vs. revoked) | Pseudo-prospective<br><br>ANOVA, Chi-square, percentages, unstated | 2 years<br><br>Clients evaluated for admission to program between 1980-1983 | Review of records | - | 68.7 |
| **Callahan, 1998**<br><br>**Connecticut Maryland New York Ohio, USA** | 585 NGRI | - | - | - | - | To identify system-level and individual-level variables associated with revocation. | Pseudo-prospective<br><br>Logistic regression | All participants followed up for at least 5 years after CR.<br><br>1987-1992 | Patient records in psychiatric facilities, and at community program. Interviews with professional staff. | OR | 31.1 |
| **Hayes, 2014**<br><br>**New South Wales, Australia** | 185 NGMI | 85.3 | 36[e]<br>Range=16-82 | - | 83.8=Schizophrenia-related psychotic illness<br>9.6=Mood disorder.<br>51.8=Comorbid substance abuse disorder<br>7.1=Borderline or mild intellectual disability | To examine the outcomes of NGMI and released on CR. | Pseudo-prospective<br><br>Survival analysis using Kaplan-Meier estimator. Chi-squared tests. | Average of 8 years.<br><br>all people found NGMI between 1990-2010 in New South Wales. | Information extracted from Mental Health Review Tribunal files. Including legal documents, reports by mental health professionals. | - | 25.9<br>48.1[x] |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 8.1=Symptoms consistent with the diagnosis of ASPD | | | | | | |
| **Jewell, 2018**<br><br>**England, UK** | 101 CD'd patients from medium secure | 82.2 | 40[a]<br>Median=28; Range=21-84 | 28.7 | 89.1=Psychotic illness<br>39.3=PD (primary or comorbid diagnosis)<br>72.3=Met criteria for substance use | Aim to evaluate the reasons ascribed to the recall and conduct exploratory investigation to identify possible predictors of recall | Pseudo-prospective<br><br>Cox regression survival techniques | Mean follow-up time of 811 days. Range 25-2246<br><br>Participants discharged from medium secure between 2007-2013. | Anonymised database of electronic medical records | HR | 44.5[x] |
| **Manguno-Mire, 2014**<br><br>**Louisiana, USA** | 193 NGRI or IST | 78.2 | 37.6[b]<br>SD=12.4 | 20.7 | 73.6=Substance use<br>57.5=Schizophrenia<br>42.5=Mental retardation<br>9.3=PD | To investigate factors related to success on CR. | Pseudo-prospective<br><br>Kruksall-Wallis. Logistic regression. | Revoked group Mdn=296 days, Non-revoked group Mdn=441 days | Client record reviewed for specific variables using a standardised form and entered into database for analysis. | OR for logistic regression | 30 |
| **Marshall, 2014**<br><br>**Maryland, USA** | 356 IAs | 78.1 | 39.62[a]<br>SD=12.31<br>Range=19-82 | 29.2 | 71.3=Psychotic disorders<br>22.5=Antisocial PD or traits | To ascertain if a predictive model could be established that would predict whether individuals on CR would return to a forensic hospital or remain in the community | Pseudo-prospective<br><br>Chi-square, ANOVA, Logistic regression | 3 year follow up data.<br><br>Files reviewed were for individuals granted their CR during 2007-2009 2009 fiscal year. | Files reviewed from Department of Health and Mental Hygiene, Office of Forensic Services were reviewed | *d* reported for some | 55[x] |
| **Monson, 2001**<br><br>**Missouri, USA** | 125 NGRI | 83 | 37.70[b]<br>SD=9.16 | 62 | 41.6=Schizophrenia<br>11.2=Bipolar<br>8=Schizoaffective<br>10.4=Other psychotic<br>2.4=No diagnosis<br>26.4=Cluster B PD | Aim to improve understanding of CR maintenance by employing survival analysis | Pseudo-prospective<br><br>Chi-square, Hierarchical logistic and cox regressions by step | Average time on CR for revoked group = 32.1months (SD=32.78). Average time on CR maintenance group | Random sample of medical & forensic records. Five individuals trained in data collection. Intercoder agreement was | - | 44 |

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| | | | | | | | | =79.81months (SD= 43.98)<br><br>Patients discharged between 1985-1998 | assessed and discrepancies resolved by 2 coders consensus. | | |
| **Parker, 2004**<br><br>**Ohio, USA** | 83 NGRI | 74 | 46.9[b]<br>Range=23-78 | - | 71=Schizophrenia<br>12=Schizoaffective disorder<br>11=Bipolar disorder<br>42= Alcohol and/or drug abuse (current or historical) | To analyse data to identify any factors associated with successful CR. | Pseudo-prospective<br><br>Univariate & multivariate logistic regression. | 5-year outcome.<br><br>The mean actual period of time in community of the IAs was 2.8 ± 1.5 years.<br>Mdn actual community tenure=2.7 years.<br><br>1996-2000 | Review of court reports and a state computer database. | OR reported for regression | 47[x] |
| **Riordan, 2006**<br><br>**England, UK** | 75 CD'd "restricted hospital order patients" | 89.3 | Median=42<br>Range=19-71 | - | Psychiatric diagnoses not given<br>42.7 = drug misuse problems | Aim to identify factors predictive of readmission for CD'd patients & formal recall to hospital. | Pseudo-prospective<br><br>Logistic regression. | -<br><br>Patients discharged from a restricted hospital order into the community between 1987-2000. | Case notes and files of patients kept at the Mental Health Unit of the Home Office. | OR | Not stated |
| **Salem, 2015**<br><br>**Québec, Canada** | 837 NCRMD | 82.4 | 35.0[c]<br>SD = 12<br>Range = 18-82 | - | 64.5=psychotic disorder<br>28.7=mood disorder<br>31=Substance use disorder<br>11.17=Axis II disorder | To investigate the impact of supportive housing during CD on the clinical and criminal outcomes of NCRMD individuals. | Retrospective longitudinal design<br><br>Cox regression | The average follow-up period for the sample was 743.86 days (SD 677.20)<br><br>Individuals found NCRMD between 2000-2005. | Review Board files | - | 34.9[x] |
| **Stoner, 2002**<br><br>**Missouri, USA** | 25 NGRI or IST | 82.1 | - | - | - | To compare rate of revocation | Pseudo-prospective | Haloperidol treatment = 29.5months | Review of computer | - | 40 |

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| | | | | | | and length of time on CR in patients treated by clozapine and haloperidol. | Chi-square, Fisher's exact test, Student's t-test | (2.46 years) on CR. Clozapine group = 53.5 months (4.46years) on CR.<br><br>Hospitalized between 1990-1999. Discharge information was taken in June 2001. | medical records. | | |
| **Tellefsen, 1992**<br><br>**Maryland, USA** | 50 IAs | - | - | - | 79.2=Schizophrenia (regional group) 50=Schizophrenia (state hospital group) 8.4=Bipolar (regional group) 33.4=Bipolar (state hospital group) | To examine the outcomes of CR'd patients. To test a predictive model for CR revocation. | Pseudo-prospective<br><br>Canonical correlation, two step-wise discriminant analysis. | -<br><br>IAs released between 1983-1984 | Records from psychiatric hospitals and community aftercare services. Inventory data collected on participants from previous study. Review of FBI arrest histories; State police records. | - | 58.3 (regionalised) 36.1 (state hospitalised) 79.2[x] (regionalised) 63.9[x] (state hospitalised) |
| **Vitacco, 2008**<br><br>**Wisconsin, USA** | 363 NGRI | 78.8 | 41.02 [a] SD=13.26 | 75.7 | 53.7=Psychosis 9.1=Antisocial PD 46.2=Substance abuse | Aimed to report on issues associated with revocation in a sample of CR'd NGRI acquittees. | Pseudo-prospective<br><br>Fisher's exact tests, Logistic regression | Community follow-up ranged from 2-6 years (*M* = 2.85 years, *SD* = 3.99 years). Participants CR'd between 2000-2004 | Independent variables collected from follow-up data maintained on each participant. | $R^2$ reported for regression | 33.9 |
| **Vitacco, 2011**<br><br>**Wisconsin, USA** | 79 NGRI | 0 | 42.76 [a] | 76.3 | 44.7=Schizophrenia 23.7=Bipolar 11.8=Depression 34.2=Comorbid substance abuse 39.5=Axis II PD 7.9= Borderline PD 7.9=Antisocial PD | To examine variables linked to the outcome of female NGRI acquittees on CR. | Pseudo-prospective<br><br>Logistic regression. | M = 4.6 years (range 3-7 years)<br><br>2000-2006 | Review of legal records. | - | 31.6 |

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| | | | | | 23.7=Not otherwise specified | | | | | | |
| **Vitacco, 2014**<br><br>**Virginia, USA** | 127 NGRI | 77.9 | 43.51[a]<br>SD=12.41 | 55.9 | 66.1=Psychotic spectrum<br>24.4=Bipolar disorder<br>3.9=Cognitive-related disorder<br>2.4=Major depression<br>2.4=Posttraumatic stress disorder<br>0.01=No diagnosis<br>79.5=More than one diagnosis<br>56.7=Substance abuse diagnosis<br>7.9=PD | To identify whether standardised risk factors and demographic factors were related to revocation or maintenance of CR. | Pseudo-prospective<br><br>Logistic regression, Multivariate survival analysis. | On CR for *M*=23.57 months, *SD*=20.21 months<br><br>All individuals who were on CR between 2007-2010 reviewed | Individual files reviewed. Risk factors were selected from a standardized list published by the Department of Behavioral Health and Developmental Services. | OR | 24.4 |
| **Vitacco, 2018**<br><br>**Oregon, USA** | 238 NGRI | 84.0 | 40.38[a]<br>SD=12.10<br>Range=19-77<br>35.52[c]<br>SD=11.59<br>Range=15-70 | 82.8 | 54.2=Psychotic spectrum<br>29.4=Mood disorders<br>7.1=Intellectual disabilities<br>4.6=Cognitive disorders<br>3.4=Substance abuse disorders<br>0.8=Anxiety disorders<br>0.004=Dissociative disorder<br>91.6=Had secondary diagnosis<br>54.2=Substance abuse disorder<br>27.31=Secondary diagnosis of PD | Aim to evaluate the effectiveness of the HCR-20 regarding outcome on sample of IAs. | Pseudo-prospective<br><br>ANOVA, Logistic regression, Cox regression. | Between 4 and 9 years.<br><br>All individuals CR'd during between 2007-2011. Follow-up review time ended January 1, 2016. | Risk assessment data (HCR-20) from Oregon State Hospital and public records for the participants. Files reviews conducted by 2 licensed psychologists. | *r*, *d,* Phi, OR | 33.6 |
| **Wiederanders (1994)**<br><br>**California, USA** | 240 NGRI & others | 84.4 | 43.3 years[f] | 60.8 | 47.2=Schizophrenia | To develop and quantify assessment measures of community functioning in CR'd patients. | Pseudo-prospective<br><br>ANOVA. | At least 2 years.<br><br>Between 1986-1992 | Authors used established and developed questionnaires: SAI, SF-JBC, F-BPRS | - | 55.4 |

N.B. "-"denotes "Not reported". IAs: Insanity Acquittees; NGRI: Not Guilty by Reason of Insanity Acquittees; NGMI: Not Guilty by reason of Mental Illness; NCRMD: Not Criminally Responsible Due to a Mental Disorder; IST: Incompetent to stand trial; CD: Conditional Discharge; CR: Conditional Release; PD: Personality disorder; ANOVA: Analysis of Variance; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, fourth edition; HCR-20: Historical Clinical Risk-20. SAI: Social Adjustment Indicators; SF-JBC: Short Form of the Jesness Behavior Checklist; F-BPRS: Forensic Psychiatric symptoms, partly developed from Overall & Gorham's (1962) Brief

Psychiatric Rating Scale; Odds ratio; HR: Hazard ratio; [A] = Age at point of CD/CR; [B] = Age point not stated; [C] = Age at index offence; [D] = Mean age at admission to aftercare clinic; [E] = Age at time of NGMI verdict; [F]= Age at time of data collection. All ages given are means unless otherwise stated. Median age given if reported and no mean given. [X]= Readmitted.

## Quality assessment and risk of bias

Results of the risk of bias assessment are reported in Table 3. This evaluation demonstrated that the foremost risk of bias was in missing data and sample size. Follow-up and measurement of independent variables were found to be a lesser risk of bias.

Six out of 18 studies reported how much data was missing; usually reporting low missing data rates or cases being excluded if they presented with missing data (Bloom et al., 1986; Hayes et al., 2014; Manguno-Mire et al., 2014; Salem et al., 2015; Vitacco et al., 2008, 2014). Thus, two thirds of studies did not report on missing data representing a significant source of bias. Data on the event of revocation is generally considered to be reliable due to this being a legal status and thus likely recorded accurately.

Most studies in the sample did not include the use of standardised assessment tools in their measurement of independent variables but did utilise retrospective review of official medical and legal records in order to extract information. For example, only 2 studies included some items from a widely used, standardised assessment tool (i.e. Historical Clinical Risk-20 Version 2 (HCR-20$^{v2}$); Webster et al., 2001) in their analyses (Jewell et al., 2018; Vitacco et al., 2018). Some more recent studies used electronic databases (Jewell et al., 2018; Manguno-Mire et al., 2014; Parker, 2004; Stoner et al., 2002). All studies sampled in this review may be subject to information bias in that the information extracted may be vulnerable to human error. Measuring or survey instruments were often described in vague terms in studies (e.g. a "standardised form"), were not available for scrutiny and the fidelity with which information was extracted was largely not subject to assessment of inter-rater reliability.

One study was rated inadequate as it did not state a follow-up period (Riordan et al., 2006). As studies have generally found that most CR failure tends to occur within 2 years of granting of CR (Callahan & Silver, 1998; Hayes et al., 2014). Studies with 2 years or more follow-up were considered optimum. Three studies had follow-up periods of less than 2 years and were considered “adequately covered” (Bertman-Pate et al., 2004; Manguno-Mire et al., 2014; Vitacco et al., 2014).

Eight studies were deemed to have an inadequate sample size (Bertman-Pate et al., 2004; Bloom et al., 1986; Jewell et al., 2018; Parker, 2004; Riordan et al., 2006; Stoner et al., 2002; Tellefsen et al., 1992; Vitacco et al., 2011). Multiple tests of significance were undertaken within various statistical analyses methods and so the risk of Type I and II errors is elevated within these studies.

Eight articles were strong regarding adequate sample size and follow-up period (Callahan & Silver, 1998; Hayes et al 2014; Marshall et al., 2014; Monson et al., 2001; Salem et al., 2015;

Vitacco et al., 2008; 2018; Wiederanders et al., 1994). One paper was inadequate on both counts (Riordan et al., 2006) and thus this study must be considered with caution.

The studies examined are heterogeneous in that they analysed data from the 1970s-2010s, different legal and mental health systems and varying revocation rates from 24.4-68.7% were found (Table 2). Some jurisdictions may revoke patients more readily or for lesser breaches or this may be a function of the time period covered in the articles included in this review as the higher revocation rates tend to be found in older papers. Conversely, RR may serve a protective and preventative function in some services and jurisdictions who intervene before deterioration in mental health leads to a new offence.

The variables examined were categorised differently across studies. Some variables were dichotomized or categorised where they could have been examined as continuous variables which would have retained more predictive power within the data. For example, one study dichotomized the construct of psychopathy when this is most appropriately observed as a dimensional construct (Vitacco et al., 2014).

In addition, two papers analysed “incidents” occurred and this included: “relapse to psychosis, substance abuse relapse, treatment non-adherence or going “AWOL”, rule or curfew violation, or arrest” (Bertman-Pate et al., 2004; Manguno-Mire et al., 2014). Thus, it was not possible to discriminate in these 2 studies whether specific events were risk factors for RR over and above others. Most other papers if including these variables analysed them separately.

Four studies used bivariate analyses only and these results should be accepted with caution as other factors were not controlled for (Bertman-Pate et al., 2004; Bloom et al., 1986; Stoner et al., 2002; Wiederanders et al., 1994). Some studies which did utilise multivariate analyses did not explicitly report which factors they controlled for in their analysis (Marshall et al., 2014; Riordan et al., 2006; Vitacco et al., 2011). Exactly half of the articles did not report any effect size statistics (Bertman-Pate et al., 2004; Bloom et al., 1986; Hayes et al., 2014; Monson et al., 2001; Salem et al., 2015; Stoner et al., 2002; Tellefsen et al., 1992; Vitacco et al., 2011; Wiederanders et al., 1994).

None of the studies differentiated between clinical or criminal reasons for revocation. Thus, the results found can only be concluded in terms of revocation in general rather than attributed to be specifically associated with criminal or clinical revocation.

Overall, the findings of these studies should be interpreted with caution regarding their generalizability to the wider CR population and across jurisdictions.

**Table 3.** *Risk of Bias Assessment*

| First Author (Year) | Sample Selection/ representativeness | Description of Sample | Follow-up | Sample Size | Missing Data | Appropriate Analysis | Measure of outcome | Measure of independent variables | Selective Reporting | Confounding factors controlled for |
|---|---|---|---|---|---|---|---|---|---|---|
| Bertman-Pate (2004)[a] | + | ++ | + | - | - | + | ++ | - | ++ | - |
| Bloom (1986) | ++ | ++ | ++ | - | + | + | + | + | + | - |
| Callahan (1998) | ++ | ++ | ++ | ++ | - | ++ | + | + | + | + |
| Hayes (2014) | ++ | ++ | ++ | ++ | + | + | + | + | + | + |
| Jewell (2018) | + | ++ | ++ | - | - | ++ | + | + | ++ | ++ |
| Manguno-Mire (2014)[a] | ++ | ++ | + | ++ | + | ++ | + | + | ++ | ++ |
| Marshall (2014) | ++ | ++ | ++ | ++ | - | ++ | + | + | ++ | - |
| Monson (2001) | ++ | ++ | ++ | ++ | - | + | ++ | + | ++ | + |
| Parker (2004) | ++ | + | ++ | - | - | ++ | + | + | ++ | + |
| Riordan (2006) | + | - | - | - | - | + | - | - | - | - |
| Salem (2015) | ++ | ++ | ++ | ++ | + | + | ++ | ++ | ++ | ++ |
| Stoner (2002) | ++ | ++ | ++ | - | - | + | ++ | ++ | + | - |
| Tellefsen (1992) | ++ | + | + | - | - | + | + | + | ++ | + |
| Vitacco (2008)[b] | ++ | ++ | ++ | ++ | + | ++ | ++ | + | ++ | + |
| Vitacco (2011)[b] | + | ++ | ++ | - | - | + | ++ | + | ++ | - |
| Vitacco (2014) | ++ | ++ | + | ++ | + | ++ | ++ | + | ++ | + |
| Vitacco (2018) | ++ | ++ | ++ | ++ | - | ++ | ++ | ++ | ++ | + |
| Wiederanders (1994) | ++ | ++ | ++ | ++ | - | + | ++ | ++ | ++ | + |

++ = Well Covered; + = Adequately Covered; - = Not Adequately Covered; N/A = Not Applicable; [a] yielded from Louisiana, USA sample but different time periods though some participants may overlap. [b] yielded from same sample; 2011 sample is a female sub-sample of the 2008 sample with further follow-up.

## Study Outcomes

The independent variables analysed were classified into the following four categories: 1) demographic 2) clinical 3) post release, and 4) forensic variables. The sections below describes the results for each of these groupings of variables. The variables are synthesized in Table 4 and 5. Please see Appendix 5 for study specific descriptions of independent variables found to have significant relationships with RR. Risk factors have been defined here as variables which are predictive of or associated with RR; protective factors as variables which are predictive of or associated with maintenance of CR.

### *Demographic variables*

Nine of 18 papers reviewed reported on age, younger age was a risk factor for RR in three articles (Hayes et al., 2014; Jewell et al., 2018; Vitacco et al., 2011); one study found younger age at admission protective (Tellefsen et al., 1992). Older age at index verdict was studied in one paper and found to be protective (Salem et al., 2015).

Eleven articles studied ethnicity; minority ethnicity was found to be a risk factor for RR in three studies (Hayes et al., 2015; Jewell et al., 2018; Monson et al., 2001); and white ethnicity protective in three articles (Callahan & Silver, 1998; Jewell et al., 2018; Tellefsen et al., 1992). All of the articles which found an association of ethnicity on revocation were deemed to have adequate sample size and follow-up period.

Sex was reported on in four studies and one study found being female to be protective for RR (Salem et al., 2015).

Seven papers analysed marital status and two papers found this to be a protective factor for RR (Callahan & Silver, 1998; Tellefsen et al., 1992).

One study looked at having medicare and social security disability and found this to be a protective factor for RR (Manguno-Mire et al., 2014).

One study analysed the effect of early maladjustment (Item H8 on HCR-20$^{V2}$) and the presence of this was found to be a risk factor for RR and the absence of this protective for RR (Jewell et al., 2018).

One study looked at levels of functioning before hospitalization and prior occupation (having some labour skills) and found higher levels of both to be protective for RR (Tellefsen et al., 1992).

### *Clinical variables*

Twelve articles analysed diagnoses of schizophrenia/mood disorders; two papers examined the relevance of schizophrenia; one concluding it was a risk factor and one a protective factor (Bertman-Pate et al., 2004; Parker, 2004).

Seven papers looked at PD/traits and four papers found presence of this to be a risk factor for RR, however, only at bivariate level (Hayes et al., 2014; Manguno-Mire et al., 2014; Vitacco et al., 2008; Wiederanders et al., 1994). One paper analysed the absence of this and found this to be a protective factor (Manguno-Mire et al., 2014).

Substance use was analysed in 16 articles and nine papers found this to be a risk factor for RR (Hayes et al., 2014; Jewell et al., 2018; Marshall et al., 2014; Riordan et al., 2006; Wiederanders et al., 1994); four studies found this at multivariate level (Callahan & Silver, 1998; Monson et al., 2001; Vitacco et al., 2008, 2018). Cannabis and stimulant abuse were found to be specifically associated with RR in one study (Jewell et al., 2018). The majority of the papers displaying these were strong regarding their follow-up period and sample size, thus these results are arguably fairly robust and representative.

Having involvement (and more frequent admissions) with psychiatric services prior to index offence was found to be a risk factor in two of the five studies which analysed this (Jewell et al., 2018; Salem et al., 2015). Having a longer period of time in community prior to first offence was analysed in one study and found to be a protective factor with very large effect size (Marshall et al., 2014). Longer length of tenure in outpatient program was found to be a significant protective factor in the two articles which analysed this variable (Bertman-Pate et al., 2004; Bloom et al., 1986).

One study found that nonadherence with hospital treatment was associated with RR (Vitacco et al., 2014).

Global Assessment of Functioning (Endicott et al., 1976; GAF) scores over 50 (moderate symptoms or less) at discharge was a protective factor in the one study which analysed this (Tellefsen et al., 1992).

One study found that symptoms of paranoia, psychosis, anxiety and depression, and blunted affect were risk factors for RR (Wiederanders et al., 1994)

Treatment with clozapine (compared to depot and haloperidol) was found to be a protective factor for RR in both studies which looked at this variable (Stoner et al., 2002; Jewell et al., 2018).

### *Post release variables associated with revocation & readmission*

Two papers analysed number of "incidents"[1] while on CR – they both found that having fewer incidents while on CR was protective for RR (Bertman-Pate et al., 2004; Manguno-Mire et al., 2014). One of the study's found that having no incidents while on CR was protective (Bertman-Pate et al., 2004). Only one of the papers found that having at least one incident and a lower number of days to first incident were risk factors for RR (Manguno-Mire et al., 2014).

Being on high or intensive supervision (vs. minimum or moderate levels) was analysed in two studies and found to be a risk factor in both articles (Vitacco et al., 2008, 2011). Previous failure while on CR was reviewed in one study and found to be a risk factor for RR (Vitacco et al., 2014).

Employment while on CR was analysed in four articles; one study[2] found unemployment to be a risk factor for RR (Hayes et al., 2014) and being employed was found to be a protective factor for RR in two studies (Callahan & Silver, 1998; Wiederanders et al., 1994).

Having social supports whilst on CR, increased scores on independence, compliance, unobtrusiveness and responsibility were found to be protective factors in the one study which reviewed these variables (Wiederanders, 1994).

Six studies reviewed living arrangements while on CR and a mixed direction of results was found. Living with family (vs. living alone) was a risk factor for RR in one study (Callahan & Silver, 1998). In contrast, another study found living with family or alone/semi-independent (compared to living in a group home or boarding home) was a protective factor for RR (Monson et al., 2001). Living with family was found to be a risk factor (Marshall et al., 2014). Independent housing (compared with supportive housing) was a risk factor for RR in one study (Salem et al., 2015) and living alone (compared to with a partner) was a risk factor in another (Riordan et al., 2006).

Length of potential CR was reviewed in one study and found to be a risk factor (Parker, 2004).

Exposure to destabilisers and stress (HCR-20$^{V2}$ items) were analysed in one study which found their presence to be a risk factor for RR (Vitacco et al., 2018).

[1] Incidents included: "relapse to psychosis, substance abuse relapse, treatment non-adherence or going "AWOL", rule or curfew violation, or arrest" (Bertman-Pate et al., 2004; Manguno-Mire et al., 2014).
[2] Due to discrepancies in the reporting of both employment and unemployment in the supplemental data of this study this variable has been interpreted as a typographical error and concluded as "unemployment" (Hayes et al., 2014).

Recall for short-term hospitalizations in non-forensic facility while on CR[3] was reviewed in two studies and was found to be a risk factor for RR in both (Vitacco et al., 2008, 2011).

### *Forensic variables associated with revocation & readmission*

Age at first offence/violence (childhood or <25 years old) was reviewed in four studies and younger age was found to be a risk factor for RR in three studies (Hayes et al., 2014; Jewell et al., 2018; Manguno-Mire et al., 2014).

Risk and dangerousness scores and dangerousness to others were analysed in two studies and both found them to be risk factors for RR (Vitacco et al., 2014; Wiederanders et al, 1994).

Number of previous charges was reviewed in three studies and found to be a risk factor in two (Vitacco et al., 2011, 2014). Number of previous violent charges was examined in only one study and was found to be a risk factor (Vitacco et al., 2014). Having previous arrests were reviewed in three articles and all found this to be a risk factor for RR (Bertman-Pate et al 2004; Manguno-Mire et al., 2014; Marshall et al., 2014).

Prior criminal history (Monson et al., 2001), previous time in prison (Hayes et al., 2014), previous conviction (Hayes et al., 2014) were each reviewed in only one study respectively and all were found to be risk factors for RR. Number of offenses was analysed in one study and was identified as a risk factor (Vitacco et al., 2018).

Higher severity of instant offense was reviewed in two studies and this was found to be a risk factor in one (Tellefsen et al., 1992). Target offense being the first offense was analysed in one article and found to be a protective factor (Callahan and Silver, 1998).

[3] These admissions were required for mental health stabilization (and occurred in non-forensic mental health settings) and were not coded in the study as CR failures because they did not involve reoffending or rule breaching.

**Table 4.**

*Synthesis of the main significant results regarding patients' characteristics, revocation and proxies*

| Variable Grouping | Variable subgrouping (No. of studies analysing the variable) | Variables | No. of studies analysing individual variables | Studies found significant results | Main significant results and direction of results at bivariate level (No. of papers) | Main significant results and direction of results at multivariate level (No. of papers) |
|---|---|---|---|---|---|---|
| DEMOGRAPHIC | Age (6) | Age (incl. Age, age at: arrest, offense, release, at CR (<35)) | 6 | Hayes (2014)<br>Vitacco (2011) | Risk (1) | Risk (2) |
| | | Birth order | 1 | Tellefsen (1992) | | Risk (1) [x] for patients discharge from state hospital |
| | Ethnicity (10) | White ethnicity | 10 | Callahan (1998) | Protective (1) | |
| | | Aboriginal and Torres Strait Islander status | | Hayes (2014) | Risk (1) | |
| | | Minority ethnicity | | Monson (2001) | Risk (1) | Risk (1) |
| | | Race | | Tellefsen (1992) | | Protective (1) [x] for patients discharge from state hospital & regional facilities |
| | Marital status (7) | Marital status/ Being married | 7 | Tellefsen (1992)<br>Callahan (1998) | Protective (1) | Protective factor (1) [x] for patients discharge from state hospital & regional facilities |
| | Social security (1) | Having medicare | 1 | Manguno-Mire (2014) | Protective (1) | |
| | | Having social security disability income | | Manguno-Mire (2014) | Protective (1) | Protective (1) |
| CLINICAL | Mental disorder diagnoses | Diagnosis of mental retardation | 4 | Bertman-Pate (2004) | Protective (1) | |
| | | Diagnosis of schizophrenia | 7 | Bertman-Pate (2004) | Risk (1) | |
| | | Mood disorder | 1 | Vitacco (2011) | | Risk (1) |
| | Personality disorder (PD) (8) | Not having a PD | 1 | Manguno-Mire (2014) | Protective (1) | Protective (1) |
| | | PD<br>Antisocial PD | 4<br>2 | Manguno-Mire (2014) | Risk (1)<br>Risk (1) | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | Vitacco (2008) | | |
| | | Antisocial personality traits | 1 | Hayes (2014) | Risk (1) | |
| | Substance use (9) | Substance abuse | 3 | Hayes (2014)<br>Wiederanders (1994) | Risk (2) | |
| | | Poly-substance abuse | 1 | Hayes (2014) | Risk (1) | |
| | | Substance abuse diagnosis | 3 | Monson (2001)<br>Vitacco (2008)<br>Vitacco (2018) | Risk (3) | Risk (1) [a]<br>Risk (1) [b]<br>Risk (1) |
| | | Substance abuse history | 2 | Callahan (1998) | Risk (1) | Risk (1) |
| | Psychiatric functioning /history | Fewer previous psychiatric hospitalizations | 3 | Bertman-Pate (2004) | Protective (1) | |
| | | Longer length of stay in outpatient program | 2 | Bertman-Pate (2004)<br>Bloom (1986) | Protective (2) | |
| | | Nonadherence with hospital treatment | 1 | Vitacco (2014) | | Risk (1) |
| | | Prior functioning (better) | 1 | Tellefsen (1992) | | Risk (1) [x] for patients discharged from state hospital & regional facilities |
| | | Adjustment at state hospital | 1 | Tellefsen (1992) | | Risk (1) [x] for patients discharged from state hospital & regional facilities |
| | | Adjustment at regional | 1 | Tellefsen (1992) | | Risk (1) [x] for patients discharge from regional facilities |
| | | Better hospital assessment at state hospital | 1 | Tellefsen (1992) | | Protective (1) [x] for patients discharge from regional facilities |
| | | GAF at state hospital discharge | 1 | Tellefsen (1992) | | Protective (1) [x] for patients discharge from regional facilities |
| | | GAF at regional discharge | 1 | Tellefsen (1992) | | Protective (1) [x] for patients discharge from regional facilities |
| | Psychiatric symptoms | Paranoid | 1 | Wiederanders (1994) | Risk (1) | |
| | | Psychotic | | Wiederanders (1994) | Risk (1) | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Anxiety & Depression | | Wiederanders (1994) | Risk (1) | |
| | | Blunted affect | | Wiederanders (1994) | Risk (1) | |
| | Medication | Clozapine treatment | 1 | Stoner (2002) | Protective (1)<br>Protective (1) [c] | |
| POST RELEASE | Incidents | 0 incidents while on CR | 1 | Bertman-Pate (2004) | Protective (1) | |
| | | Fewer incidents while on CR | 2 | Bertman-Pate (2004)<br>Manguno-Mire (2014) | Protective (2) | Protective (1) |
| | | At least one incident while on CR | 2 | Manguno-Mire (2014) | Risk (1) | |
| | | Lower number of days to first incident | 2 | Manguno-Mire (2014) | Risk (1) | |
| | CR functioning | Being on high or intensive supervision (compared to minimum or moderate) | 2 | Vitacco (2008)<br>Vitacco (2011) | Risk (2) | Risk (2) |
| | | Previous failure on conditional release | 1 | Vitacco (2014) | | Risk (1) [a]<br>Risk (1) |
| | | Recall for short-term hospitalisations in non-forensic facility while on CR | 2 | Vitacco (2008)<br>Vitacco (2011) | Risk (1) | Risk (1) |
| | | Breach prior to CR | 1 | Hayes (2014) | Risk (1) | |
| | | Independent and compliance | 1 | Wiederanders (1994) | Protective (1) | |
| | | Unobtrusiveness | 1 | Wiederanders (1994) | Protective (1) | |
| | | Responsibility | 1 | Wiederanders (1994) | Protective (1) | |
| | | Social Supports on CR | 2 | Wiederanders (1994) | Protective (1) | |
| | Employment | Employed at CR | 4 | Callahan (1998)<br>Wiederanders (1994) | Protective (2) | Protective (1) |
| | | Being unemployed at CR | | Hayes (2014) | Risk (1) | Risk (1) |
| | Stress & destabilisers (1) | Exposure to destabilisers (HCR-20) | 1 | Vitacco (2018) | Risk (1) | Risk (1) [a] |
| | | Stress (HCR-20) | | Vitacco (2018) | Risk (1) | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Living situation (3) | Living with family (compared to living alone)<br>Living with family or alone/semi-independent (vs group home or boarding home) | 3 | Callahan (1998)<br>Monson (2001) | Risk (1)<br>Protective (1) | |
| FORENSIC | Age at first offence (<25 years) (3) | Age at first offence (<25 years)<br>"Younger age at first offence" | 3 | Hayes (2014)<br>Manguno-Mire (2014) | Risk (2) | |
| | Dangerousness (2) | Risk & dangerousness | 1 | Wiederanders (1994) | Risk (1) | |
| | | Dangerousness to others | 1 | Vitacco (2014) | | Risk (1) |
| | Forensic history (12) | Number of previous violent charges | 1 | Vitacco (2014) | | Risk (1) [a]<br>Risk (1) |
| | | Number of previous charges | 3 | Vitacco (2014)<br>Vitacco (2011) | | Risk (1) [a]<br>Risk (1) |
| | | Number of offenses | 1 | Vitacco (2018) | | Risk (1) [b] |
| | | Severity of instant offense | 2 | Tellefsen (1992) | | Risk (1) [x] for patients discharge from regional facilities |
| | | Target offense was first offense | 1 | Callahan (1998) | Protective (1) | |
| | | Prior criminal history | 1 | Monson (2001) | Risk (1) | Risk (1) |
| | | Previous arrests | 2 | Bertman-Pate (2004)<br>Manguno-Mire (2014) | Risk (2) | |
| | | Previous prison | 1 | Hayes (2014) | Risk (1) | |
| | | Previous conviction | 1 | Hayes (2014) | Risk (1) | |

[a] Predicting time to revocation [b] Imminence to revocation [c] Longer time on CR [x] Predicting revocation. "Incidents" included "relapse to psychosis, substance abuse relapse, treatment non-adherence or going AWOL, rule or curfew violation, or arrest". Risk factors have been defined here as variables which are predictive of or associated with revocation. Protective factors have been defined here as variables which are predictive of or associated with maintenance of CR.

**Table. 5**

*Synthesis of the main significant results regarding patients' characteristics, readmission and proxies*

| Variable Grouping | Variable subgrouping (No. of studies analysing the variable) | Variables | No. of studies analysing the variable | Studies found significant results | Main significant results and direction of results at bivariate level (No. of papers) | Main significant results and direction of results at multivariate level (No. of papers) |
|---|---|---|---|---|---|---|
| DEMOGRAPHIC | Age (5) | Younger age (≤ 38) | 4 | Jewell (2018) | | Risk (1)[a] |
| | | Older age at index verdict | | Salem (2015) | | Protective (1)[x] |
| | | Age at admission (25-35) | 1 | Tellefsen (1992) | | Protective (1) for patients from regional & state hospital |
| | Ethnicity (2) | Non-white ethnicity | 2 | Jewell (2018) | | Risk (1)[ab] |
| | | White ethnicity | | Jewell (2018) | | Protective (1) [a] |
| | Sex (4) | Sex/ Being female | 4 | Salem (2015) | | Protective (1)[x] |
| | Early maladjustment (1) | HCR-20 H8 early maladjustment | 1 | Jewell (2018) | | Risk (1)[ab] |
| | | No early childhood maladjustment | 1 | Jewell (2018) | | Protective (1) [a] |
| | Functioning before hospitalization (1) | Functioning before hospitalization | 1 | Tellefsen (1992) | | Protective (1) for patients from state hospital |
| | | Occupation/have some labour skills | 1 | Tellefsen (1992) | | Protective (1) for patients from state hospital |
| CLINICAL | Psychiatric diagnosis (5) | Diagnosis of schizophrenia/ psychosis etc | 5 | Parker (2004) [z] | Protective (1) | Protective factor (1) |
| | Substance use (7) | Substance abuse disorder/ diagnosis | 4 | Hayes (2014)<br>Jewell (2018) | Risk (1) | Risk (1)<br>Risk (1)[a] |
| | | Substance use (present/ while on CR) | 3 | Marshall (2014)<br>Riordan (2006) | Risk (1) | Risk (2) |
| | | Specifically, cannabis | 1 | Jewell (2018) | | Risk (1)[a] |
| | | Specifically, stimulant abuse | 1 | Jewell (2018) | | Risk (1)[a] |
| | Psychiatric history (6) | Being known to mental health services (before offences) | 1 | Jewell (2018) | | Risk (1)[a] |
| | | Number of/ having a psychiatric admission prior to the index admission/ index verdict | 4 | Jewell (2018)<br>Salem (2015) | | Risk (1)[a]<br>Risk (1)[x] |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Longer period of time in the community prior to their first psychiatric admission | 1 | Marshall (2014) | Protective (1) | Protective (1) |
| | | Fewer community psychiatric admissions during CR | 1 | Marshall (2014) | Protective (1) | |
| | Psychiatric functioning (3) | Residual symptoms at CR | 1 | Hayes (2014) | Risk (1) | Risk (1) |
| | | Present self-harm | 1 | Riordan (2006) | | Risk (1) |
| | | GAF score (>50) at discharge from regional hospital | 1 | Tellefsen (1992) | | Protective (1) for patients from regional hospital |
| | | Adjustment at state hospital | 1 | Tellefsen (1992) | | Protective (1) for patients from regional hospital |
| | | Hospital assessment at regional hospital (considerable improved at discharge) | 1 | Tellefsen (1992) | | Protective (1) for patients from regional hospital |
| POST RELEASE | Employment (3) | Unemployed at CR | 3 | Hayes (2014) | Risk (1) | |
| | Medication (1) | Treatment with a depot medication | 1 | Jewell (2018) | | Risk (1)[ab] |
| | | Treatment with clozapine | 1 | Jewell (2018) | | Protective (1) [a] |
| | CR functioning (2) | Length of potential CR | 1 | Parker (2004)[z] | Risk (1) | Risk (1) |
| | | Noncompliance with treatment (i.e. Housing & family placement) | 1 | Marshall (2014) | | Risk (1) |
| | Living situation (3) | Living with family (than community housing) / live-in significant other | 1 | Marshall (2014) | Risk (1) | |
| | | Living alone compared to with partner | 1 | Riordan (2006) | | Risk (1)[c] |
| | | Independent housing (compared with supportive housing) | 1 | Salem (2015) | Risk (1)[x] | |
| FORENSIC | Early violence (1) | Early violence | 1 | Jewell (2018) | | Risk (1)[a] |
| | | Young age at first violent incident (Item H2, HCR-20v2) | 1 | Jewell (2018) | | Risk (1)[a] |
| | Forensic history | Had arrests compared to no arrests | 1 | Marshall (2014) | Risk (1) | Risk (1) |

[a]Time to recall, [b]Risk of recall, [c]Recall, [x]Risk of readmission [z]= outcome of hospitalization or arrest. Some studies looked at outcomes of revocation and readmission (Hayes et al., 2014; Parker, 2004, Tellefsen et al., 1992; Vitacco et al., 2014) hence the total number of studies for each subgroup adding up to less than the combined total e.g. ethnicity combining to 11 and not 12 papers.

**Pathways to revocation & return to hospital: an exploratory model**

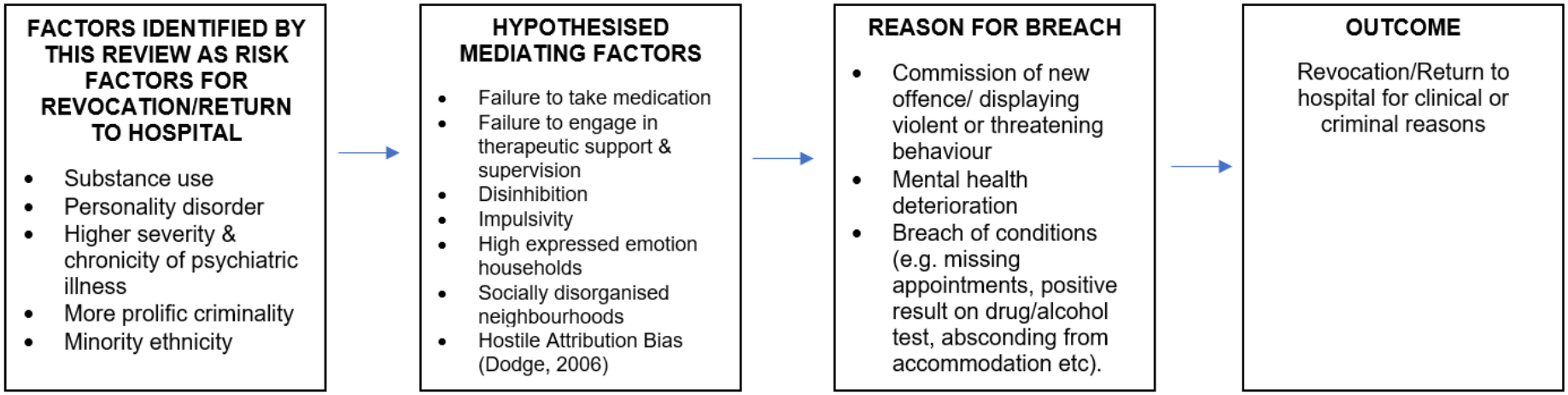


*Figure 2. Pathways to revocation & return to hospital*

The above figure denotes a visual summary of the risk factors for RR identified from evidence in the literature in this review. Possible hypothesised mediating factors (identified by the authors) between the risk factors identified by the review and reasons for breach and outcome are then delineated.

## Discussion

This review examined a wide range of studies on the factors associated with RR.

### Demographic variables

A highly significant finding was that minority ethnicity was found to be a risk factor and white ethnicity to be a protective factor in 3 articles each (4 at multivariate level). There are likely to be complex, multifactorial interactions between several factors which have produced this result. For example, systemic variables such as socially disorganized neighbourhoods which display destabilizing characteristics (low income, concentrated rental housing, high levels of unemployment, poor educational opportunities and attainment) may be a mediating factor between ethnicity and RR. Being released to socially disorganized environments has been demonstrated to be linked to increased frequency of return to inpatient care in this population (Melnychuk et al., 2009). There may also be an interaction between increased risk for psychosis (Leaune et al., 2019) and poorer outcomes (Morgan et al., 2017) in ethnic minorities and the findings below regarding higher severity and chronicity in illness.

Younger age was a risk factor for RR in 3 articles and 1 study found this to be protective when age at admission was 25-35 (this paper was rated inadequate for sample size and missing data; Tellefsen et al., 1992). Older age at index verdict was found to be protective in one study. It may be that these findings suggest that those who become unwell at a younger age may tend to have more severe illness and poorer coping (or opportunity to learn healthy coping due to young age of onset). These findings fit with previous research that has shown than compared to early-onset psychosis (before age 45), late-onset (age 45+) psychosis occurs less often in a context of negative affectivity, emotional dysregulation indicating potential variances in aetiology and more adaptive premorbid coping styles (Köhler et al., 2007).

Seven papers analysed marital status and 2 papers found this to be a protective factor for RR; though more than two thirds of the studies that investigated this variable found no significant relationship. However, both papers that found a significant result were older (1992, 1998) and marriage rates have generally lowered since the data was collected for these papers and many papers did not consider unmarried cohabiters. Households and relationships of high expressed emotion (HEE) are associated with rehospitalization (Wang et al., 2017). Thus, it appears possible that it may be the quality

of relationships that determine risk or protective effect for RR, rather than marital status itself.

One study analysed the effect of early maladjustment (Item H8 on HCR-20$^{V2}$) and the presence of this was found to be a risk factor for RR and the absence of this protective for RR (Jewell et al., 2018). Indeed, this is in line with higher levels of childhood adversity being significantly associated with a range of other negative outcomes such as criminal convictions, problematic use of alcohol or drugs, and suicidal and self-injurious behaviour (Karatzias et al., 2019).

## Clinical variables

Twelve articles analysed diagnoses of schizophrenia/mood disorders; two papers found schizophrenia to be significant factor for RR in opposite directions (Bertman-Pate et al., 2004; Parker, 2004). The majority of papers found no significant effect. This may be due to schizophrenia/psychosis being the most common diagnosis in this population (between 44.7-89.1%, Table 2) and the use of different or unclear classifications systems across the literature. Interestingly, a follow-up study of the same aftercare clinic in Louisiana which initially found schizophrenia to be associated with revocation (Bertman-Pate et al., 2004) did not find a significant effect 10 years later (Manguno-Mire et al., 2014). Perhaps, over the long-term factors such as substance use and PD become predictive and/or account for more of the variance in RR.

PD diagnosis and traits (including specifically antisocial) were found to be a risk factor for revocation and not having a PD a protective factor at multivariate level. It is possible that higher levels of impulsivity and disinhibition implicated in PD may mediate rule breaching, substance use, and mental health deterioration which may then lead to RR. Three studies investigated antisocial PD/traits specifically and two were among those studies to find PD a risk factor. Other possible mediators which may increase the likelihood of RR include: the anti-authority nature of this presentation where respect for rules, the wish to adhere to social norms or maintain positive relationships with caregivers may be limited and pro-criminal attitudes higher. One hypothesised pathway to RR in this group may be by way of aggressive behaviour which occurs as a function of attributing hostile intent to others challenging behaviour (Dodge, 2006). Experiences which promote a hostile attributional style are hypothesised to include being victim to physical abuse during childhood, modelling of these attributions by adults and peers, being raised in cultures which encourage and condone retaliation, self-defence, and

personal honour and failure in significant life tasks (Dodge, 2006). Which is in keeping with high levels of childhood adversity in this population (Karatzias et al., 2019) and the association between this and PD (Hengartner et al., 2013). Therefore, PD may be a risk factor for RR but also a product of childhood adversity. Hostile attribution bias may also mediate difficulty in engagement with treatment and supervision which again may lead to RR if requirements of CR are breached.

All studies (9/16) which found significant results regarding substance use found this to be a risk factor for RR. Substance use has been found to account for a large quantity of variance in the prediction of violence in the community by those with psychosis (Fazel et al., 2009). Thus, the powerful disinhibitory effects of substance use may result in violence and deterioration in mental health leading to RR.

Around half of studies which investigated prior psychiatric hospitalizations before first offence found significant results; finding that being known to mental health services and higher number of psychiatric hospitalizations prior to index admission was a risk factor and having fewer prior hospitalizations was a protective factor. These findings may indicate that those who are more likely to be RR'd may become ill at a younger age and have more premorbid risk factors (e.g. less effective coping style (Köhler et al., 2007), less stably maintained on medication etc). Furthermore, those for whom their index admission is their first may become unwell at a later age (e.g. singular psychotic episode in the context of drug use) and have more protective factors such as more adaptive coping. This also fits with the finding that a score of over 50 (moderate symptoms or less) on the GAF at discharge as a protective factor in the one study which reviewed this. Furthermore, increased positive symptoms (including threat control override symptomatology) have consistently been demonstrated as antecedents for aggressive behaviour in high-risk community patients (Hodgins et al., 2003; Swanson et al., 2006), community forensic samples (Lincoln & Hodgins, 2008) and forensic inpatients (Smith et al., 2020). Therefore, higher levels of chronicity and severity of illness as implied by the findings of this review increases the risk of aggressive behaviour and thereby likely the risk of RR in response to aggression.

Both studies which examined clozapine treatment found this to be a protective factor in terms of RR. This is in keeping with other findings on clozapine's protective effect on reducing readmission, bed days, crime-free time, improved clinical functioning, and aggressive behaviour (Howner et al., 2020; Kesserwani et al., 2019; Siskind et al., 2019). The literature on clozapine is subject to high risk of bias in general as the effect of

clozapine may be underestimated due to patients in clozapine trials tending to be non-responders to traditional antipsychotics (Howner et al., 2020) thus the results found here may be fairly robust. However, clozapine also presents risk of adverse side effects such as sialorrhea, sedation, weight gain, and some potentially life-threatening side effects including seizures, agranulocytosis or granulocytopenia, myocarditis, and gastrointestinal hypomotility (De Berardis et al., 2018).

## Post release variables

The two studies which examined “incidents” whilst on CR both found that these were associated with revocation, as was having fewer days to first incident. This may be a function of impulsivity in PD and disinhibition from substance use which this review has identified as risk factors for revocation.

Both studies which investigated supervision level found that being on high or intensive levels of supervision found this to be a risk factor for revocation. One study looked at previous failure while on CR and found this to be a risk factor for revocation. These findings suggest that those who are revoked are generally considered riskier before they are revoked and in need of higher levels of supervision which links to the HCR-20v3 items C5 and R4 “Treatment and supervision response” and associated literature (Douglas et al., 2013).

Concerning employment, being employed was found to be associated with maintenance of CR in 2 studies (Callahan & Silver, 1998; Wiederanders et al., 1994) and being unemployed was found to be associated with revocation and readmission on one study (Hayes et al., 2014[1]). Informal social control theory posits that the protective effect of employment is contingent on specific factors which likely increase social control; job stability, job commitment, earnings, and ties to work (Sampson & Laub, 1990).

Having social supports whilst on CR, increased scores on independence, compliance, unobtrusiveness and responsibility were found to be protective factors in the one study which reviewed these variables (Wiederanders, 1994). This perhaps reflects a generally higher level of functioning and more effective coping style which aids successful maintenance of CR. Fitting with this, recall for short-term hospitalizations in non-forensic facility while on CR was found to be associated with RR in both studies which examined this thus adding additional store to the idea that those who are more likely RR’d experience a generally lower level of functioning compared to those who maintain CR successfully.

One study investigated exposure to destabilisers and stress (HCR-20$^{V2}$ items) and found that these were a risk factor. This makes intuitive sense as these factors are evidenced to predict violence (Webster et al., 2001) and thus commission of violence may lead to revocation/return to hospital.

Living with family produced a mixed direction of results in the small number of studies which looked at this variable (5/6 studies found a significant result). Overall, living independently (compared to living with family or in supportive housing) was more often found to be a risk factor than a protective factor. There may be a mediated relationship between level of expressed emotion (EE) in the household and the association between family placements and RR which has been unexplored in these studies. HEE is associated with rehospitalisation in people with schizophrenia (Wang et al., 2017). Thus, the mixed direction of results found in this review may be explained by those in HEE family placements being more likely to experience psychiatric decompensation and thus RR whilst those living in low EE environments more likely to maintain CR. Two studies identified that living alone (compared to with partner and supportive house) were risk factors for RR. This could be for several reasons such as lack of social support, limited supervision, and limited opportunity for external reality testing of unusual experiences and beliefs thereby increasing the risk of mental health deterioration and therefore need for readmission.

In addition, patients released to specific, socialy disorganised neighborhoods have been shown to be more frequently rehospitalised (Melnychuk et al., 2009). Charactersitics of these neighbourhoods (e.g. low income, high unemployments, poor educational attainment, higher level of rental properties, access to illegal substances) may act to destabilize individuals and thus lead to RR.

### Forensic variables

Four studies examined age at first offence and 3 found that young age at first offence was a risk factor for RR. This may reflect higher levels of childhood adversity being associated with subsequent criminal convictions, and problematic use of alcohol or drugs (Karatzias et al., 2019) and later anti-sociality (DeLisi et al., 2019).

The vast majority of papers which analysed forensic variables (e.g. previous arrests, convictions, charges, criminal history, higher severity of instant offence and measures of dangerousness) found they were all significant risk factors for RR (many at multivariate level). With the exception of the target offense being the first offense which was analysed

in one study only and found to be a protective factor for revocation (Callahan and Silver, 1998). Overall, these findings provide evidence that those who are RR'd have generally higher levels of anti-sociality compared to those who are able to maintain CR.

### Pathways to revocation & return to hospital: an exploratory model

The proposed exploratory model represents a foundation point for future research that can link the current knowledge gap and assist in informing clinical implications to promote protective factors and identify those at high risk of RR in order to minimise recidivism and increase quality of life.

### Context of findings

The current review has revealed somewhat consistent findings regarding substance use, PD traits, higher severity and chronicity in psychiatric illness and more prolific criminality being significant risk factors for RR. Protective factors identified included: white ethnicity, being married, being in receipt of social security, not having PD, longer tenure in outpatient programmes, clozapine treatment, having fewer incidents while on CR, being employed or having previous labour skills, and scoring 50 or above on the GAF (moderate symptoms or less) at CR. These factors may indicate generally higher levels of functioning and more adaptive coping skills before coming in to FMH services. Further investigation is required in order to test the robustness of these identified relationships. Overall, the consistency of the findings in the context of the research question have been largely congruent with the exception of living situation and diagnosis of schizophrenia.

The quality of research in this area is limited in that it consists of cross-sectional studies which are constrained by information bias, missing data, inadequate samples sizes, lack of effect size reporting, lack of standardised measures to aid comparison of variables across samples, bias of samples towards North America, and lack of differentiation between clinical and criminal reasons for RR. Thus, conclusions are drawn with reference to revocation for any reason rather than for criminal or clinical reasons specifically (Marshall et al., 2014). Some studies and jurisdictions include relapses of mental illness as reason for revocation (Bloom et al., 1986; Callahan & Silver, 1998; Manguno-Mire et al., 2014; Vitacco et al., 2018) and others manage relapses of mental illness by admission to hospital without revocation of CR (Hayes et al., 2014; Vitacco et al., 2008; 2011). The literature demonstrates varying methods of measuring variables which are difficult to compare. Large overlap in reasons for instigating revocation and

small sample size have been cited as prohibitive factors in the examination of differences in factors associated with or predictors of criminal vs clinical revocation/recall (Jewell et al., 2018).

The generalisability of the studies in this review and findings from them must be interpreted with caution. The literature in this area suffers from the same weaknesses which can be found in the wider literature in that this is a relatively small and over-researched population. However, the data in these studies was collected routinely for clinical purposes initially so this area of the literature is unlikely to be limited by demand characteristics or practice effects compared to other areas of the FMH literature.

## Limitations

There are several limitations of this systematic review which must be considered when interpreting the findings. Firstly, a meta-analysis was not possible as varied definitions meant limited overlap in the variables examined by different papers.

Another weakness of this review is that it included only papers written in English thus potentially valid and valuable findings from papers written in other languages may have been overlooked (Liberati et al., 2009).

In addition, unpublished literature was not included and as such the studies sampled in this review may be subject to publication bias and the balance of findings revealed may be skewed in favour of positive results. However, this method has the advantage of ensuring only robust peer-reviewed studies were included. A strength of this review is the inclusion of a second reviewer which ensured a higher level of scrutiny of the papers sampled and a more balanced final result.

The comprehensiveness of the search in a systematic review has large implications for the validity of the review (Hemingway & Brereton, 2009). In this review, a variety of databases were searched with comprehensive search terms and the reference lists of included papers were examined for additional articles for inclusion. However, due to the infinite series of search terms that could be used given the breadth of the area it is possible that some relevant articles may be missing.

This review attempted to make sense of findings from studies from differing jurisdictions and continents. These are difficult to draw exact comparisons between as they present data and findings from across different legislative areas and time periods. Though it was

possible for a wide range of outcome variables to be taken into account including proxies of RR (e.g. time to recall, imminence to revocation).

This review included papers from the inception of databases onwards, thus many older papers (and thus old data sets) were reviewed. This data may not apply to the current population and services due to changes over the second part of the 20th century whereby deinstitutionalization and major changes occurred in mental healthcare provision (Fakhoury & Preibe, 2007). However, as the literature is very limited it was important that all data was included to provide the first overarching and comprehensive review of the area.

### Future research

Future research in this area may benefit from investigating the relationships between independent variables, mediating factors and specifying the revocation outcome (i.e. clinical or criminal reason for revocation). This may shed light upon any mediating factors (e.g. destabilizing characteristics such as EE, quality of relationships, the level of social disorganisation in neighbourhood upon CR) between independent variables (e.g. ethnicity, housing placement on CR) and the overall risk of revocation (criminal vs clinical reasons). Further, cohort/ prospective study designs may be of value in order to take analyses a step further as cohort design and cross-validation would allow for a prediction model to be derived from one sample and then validated in a second sample.

In addition, females are under-represented in most studies in this review and may have different needs from the male participants under study. Thus, further analysis of the risk and protective factors for RR in females would be valuable as most of the research undertaken is on males and thus interventions based on these findings may not meet the needs of females (de Vogel, & Nicholls, 2016).

Further investigation of the impact of different support upon CR (e.g. follow-up on non-attendance, supported accommodation, access to community nursing) on revocation rates would be of value, particularly in the area of substance use.

Future studies should include standardised risk assessment tools (e.g. HCR-20) as they offer a systematic method for ascertaining empirically validated risk factors and this would allow for the results of studies to be more readily compared due to the similarity of variables being studied. Multi-site/cross-jurisdiction studies would add to the validity and representativeness of the literature in addition to ensuring sample sizes are large

enough for several statistical tests to be carried out without inflating the risk of Type II errors.

Follow-up should be at least two years in future evaluations as previous research (Callahan & Silver, 1998; Hayes et al., 2014) has shown that if revocation occurs it typically occurs within 2 years of CR being granted.

Variables should be categorized appropriately or remain continuous in form. For example, events should be categorised as individual variables (i.e. breached substance testing) rather than one variable (i.e. “incidents”) covering several events which means that it is not possible to derive the individual predictive power of individual variables. In addition, care should be taken when defining variables to consider the implications for the study’s power.

Future studies should include variables related to community functioning (e.g. employment, housing type) while on CR in order to ensure there are some independent measures which are entirely independent of the outcome variables (e.g. revocation) in order to avoid criterion contamination. As often previous research has included only or mainly variables which are related to revocation in some way such as substance use on CR, and non-compliance with treatment.

## Clinical implications

One of the key purposes of this review was to identify risk and protective factors with the view to aiding services in directing their resources. Supporting individuals to increase their functioning in terms of quality of personal relationships, mental health, occupational skills and employability, treatment with clozapine (if appropriate), reducing substance use and improving access to social security may offer some protection from RR. For example, supported occupation programs may increase social control by giving job stability, commitment, and ties to work (Sampson & Laub, 1990) and psychological interventions for managing emotional dysregulation (Linehan, 1993), improving reflective functioning (Bateman & Fonagy, 2004), and ceasing repeated self-defeating behavioural patterns for presentations consistent with PD (Young et al., 2003). Longer tenure in outpatient programmes is supported by the evidence found here thus services should consider this. Although social inequalities for factors such as ethnicity are more difficult to ameliorate, they can be addressed through intervention at a systemic level.

## Conclusion

The main findings of this review are that higher substance use, PD/ traits, severity and chronicity in psychiatric illness, criminality and minority ethnicity are significant risk factors for RR. Protective factors identified were: white ethnicity, being married, being in receipt of social security, not having PD, longer stay in outpatient programme, clozapine treatment, having fewer incidents while on CR, being employed or having previous labour skills, and scoring 50 or above on the GAF (moderate symptoms or less) at CR.

Housing arrangements during CR have produced a mixed direction of results across studies and so findings on this area remain inconclusive. It is possible that factors such as HEE and the impact of social isolation on mental health mediate the relationship between RR and housing placement/type and this should be investigated further.

Quality of future research in the area would be improved with prospective study designs, use of standardised measures (e.g. HCR-20), inclusion of variables independent from RR (e.g. employment while on CR, housing type), female samples, and discrimination of the reason for RR associated with independent variables.

Suggestions for clinical practice include identification of individuals with risk factors for RR and promotion of protective factors (e.g. support with developing good quality personal relationships, occupational skills, clozapine treatment (if appropriate) and access to social security).

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**Journal Article 2: Empirical Study**

# Exploring experiences of those living under compulsion order and restriction order (CORO) in forensic mental health services in Scotland: An Interpretative Phenomenological Analysis

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## Abstract

Compulsory treatment (CT) presents an ethical quandary and thus far research has not demonstrated reduced readmission or length of inpatient stays, though some value has been shown in administering outpatient treatment. Those in forensic services and particularly those under restriction orders face the greatest constraints on their liberty with detention imposed “without limit of time”, unlike time-limited sentences in the prison system. There is a dearth of research exploring patients’ perspectives of CT and particularly the most restrictive forms of this. The current study used interpretative phenomenological analysis to analyse interviews with participants about their experiences of living under restriction. Results derived four superordinate themes; (1) *How did I end up here?* (2) *Impact: Power, Punishment and Protection* (3) *Surviving and Adapting* (4) *Recovery*. The results are reviewed in the context of extant findings; clinical implications and areas of future research are discussed.

# Introduction

## Compulsory treatment

Compulsory treatment (CT) for mental illness can be defined as legally required medical and/or psychosocial care and treatment in hospital. Since the 1980s there has been an international move towards CT in the community (Churchill et al., 2007). CT is extant in most mental health systems within developed countries with community treatment orders (CTOs) being present in more than 70 countries internationally (Mikellides et al., 2019). CTOs were initially hypothesised as one way of addressing problems resulting from deinstitutionalization; increased prevalence of mental illness in homeless and prison populations, those who pose risk of harm to others in the community and the revolving door syndrome (Geller, 2000). However, meta-analysis and systematic review of CTOs concluded that there was no evidence of benefit for patients, nor was there consistent evidence that CTOs reduce rehospitalisation or length of inpatient admission thus casting uncertainty over the utility and ethical position of CTOs (Barnett et al., 2018; Rugkåsa, 2016). However, there is limited evidence that CTOs may be of some value in enforcing outpatient treatment, increasing treatment attendance and increased community service provision (Barnett et al., 2018). This is a complex area and there is much debate regarding the factors which impact the outcome of CTOs. For example, they are used most commonly for patients with psychotic disorders who lack insight, capacity to consent and who by the very nature of their illness are more likely to experience relapse and return to hospital (Mikellides et al., 2019).

Some contend that the principles of modern mental health legislation – such as the Mental Health (Care and Treatment) (Scotland) Act 2003 (MHCT Act) - have engendered a fundamental change in the culture of detention, increasing transparency and applying the decision to greater scrutiny (Scottish Government Social Research [SGSR], 2009). Others posit that CT for mental illness is biased, inequitable, paternalistic, and likely to increase levels of coercion used in psychiatry. Thereby, further reducing the liberty and self-determination of people with mental illness (Lawton-Smith et al., 2008). Some have contended that it may contravene the UN Convention on the Rights of Persons with Disabilities, and needs to be reconsidered due to the intended result of community compulsion (i.e. reduced hospitalizations and relapse) being unsupported in over 60 methodologically strong studies (Newton-Howes & Ryan, 2017; Rugkåsa & Burns, 2017; Szmukler et al., 2014).

## Issues in forensic mental health

In forensic mental health (FMH) settings, patients may be detained involuntarily for extensive periods of time, potentially life long. This detention serves a dual purpose; care and treatment for the individual and protection for the public. Such prolonged detention poses several ethical quandaries. Not least that individuals often stay longer in these settings than they would do if they had received a prison sentence for their index offence (Völlm et al., 2016). Only four European countries (Croatia, Italy, Portugal, Spain) limit the length of admission in forensic mental health care (FMHC) to the length of prison sentence an individual without mental disorder would have served if found guilty of the same offence (Sampson et al., 2016). In a sample of forensic psychiatry experts in 18 European countries, it was noted that some individuals reside in FMHC for most of their lives if not indefinitely (e.g. Latvia, Belgium, Switzerland) (Sampson et al., 2016). In addition, it is often uncertain whether the interventions available will benefit the individual however they are detained because risk management concerns often offset the best interests of the individual (Völlm et al., 2016). For example, there may be very limited therapeutic input available to the patient or the input has already been tried however individuals remain under the auspices of a restriction order/hospital order for many years (Tomlin et al., 2018; Völlm et al., 2016). Case law of the European Court of Human Rights states that patients can be detained in psychiatric settings - even if this consists only of a 'therapeutic milieu' - for as long as this treatment is available (Hutchison Reid v the United Kingdom (2003), 37 EHRR 9; MD v Nottinghamshire Healthcare NHS Trust (2010) UKUT 59 (AAC)) (Tomlin et al., 2018; Völlm et al., 2016).

## Compulsion Order and Restriction Order

In Scotland, a Compulsion Order may be granted when an offender has a mental disorder, where medical treatment which would likely prevent the mental disorder deteriorating or improve any symptoms of the disorder is available, where if this treatment were not provided there would be significant risk to self or others, and that the making of the order is necessary in respect of the offender. The Court may also grant a Restriction Order in addition to a Compulsion Order (CORO) where an individual poses an ongoing risk of serious harm to others; this serves the purpose of public protection (Scottish Executive, 2005). Restriction orders are "without limit of time" meaning that they could and in some cases do last indefinitely. Individuals can only be discharged to the community ("conditional discharge" [CD]) or discharged completely ("absolute

discharge") by a Mental Health Tribunal deciding to vary the restriction order from hospital to community-based or revoking the order entirely.

While subject to CORO the Scottish Government is involved in the monitoring and management of these patients. For example, an individual under CORO can only be given periods of time outside of hospital or be transferred to another hospital with express approval of the Scottish Ministers applied for by their Responsible Medical Officer (RMO, their Consultant Psychiatrist). Typically, their discharge to the community is contingent on being subject to and complying with several "compulsions" (e.g. their residence, medical treatment, alcohol and drug screening etc) and "restrictions" (e.g. approved travel areas and restricted areas, the activities they can engage in, which private residences they can enter etc). If a person violates any of these conditions, they are then subject to recall to hospital by the Scottish Ministers. Generally, CD occurs when an individual has demonstrated improvement in mental state, engagement in psychosocial treatments and made their way through the Scottish forensic estate (high, medium, and low secure care). However, a small number of individuals remain in hospital and do not attain CD due to ongoing levels of risk and/or acute mental illness.

In 2018, there were approximately 290 restricted patients in Scotland at any one time (Scottish Government, 2018). In the 2013 census of forensic inpatients in Scotland there were 182 patients under CORO and the mean age was 45years old (J. Pitcairn, personal communication, August 3 2018). Sixty-seven were detained in low secure wards, 55 in medium, and 60 in high security. These figures do not include CD'd outpatients living in the community. Some other jurisdictions utilise procedures similar to CORO such as the Section 37/41 orders in England, preventive detention in Germany (Steinböck, 2009; Basdekis-Jozsa et al., 2013), and indefinite involuntary treatment in New Zealand (Saya et al., 2019).

## The forensic mental health population

The FMH population internationally presents with high levels of psychiatric comorbidity, substance misuse, and childhood adversity/trauma (Garieballa et al., 2006 Ogloff et al., 2015). A census of all Scottish forensic inpatients found that a psychotic disorder was the foremost primary diagnosis (86.4%) (Karatzias et al., 2019). Eighty-six per cent were identified as having a history of problematic drug or alcohol use. There was a high prevalence of childhood adversity (79.2%); physical abuse was reported in 40.1% of cases, sexual abuse in 22.8%, and parental drug/alcohol misuse in 25.1%. Regression

analyses demonstrated that higher levels of childhood adversity were significantly associated with problematic use of drugs or alcohol, suicidal and self-injurious behaviour, self-reported abuse of animals, and increased criminal convictions. These findings may underrepresent the trauma history of this population as census research is subject to information bias. Nonetheless, trauma informed care and practices are essential in order to meet the needs of this group (Morrison et al., 2003; Muskett et al., 2014).

A systematic review of international data showed that the manner and extent to which individuals experienced FMHC as restrictive was affected by whether the intention of the care was more custodial or caring (Tomlin et al., 2018). A study exploring perceptions of recovery in FMHC in Scotland revealed that patients perceived power imbalances between systems and themselves, a sense-making process between the past events and the present, a process of reconfiguring relationships with others, differences in what participants considered recovery to be compared to traditional definitions and wanting to feel safe and to care for others (Stuart et al., 2017). Mezey and colleagues (2010) revealed that those in FMHC in England considered medication, relationships with staff and patients, psychological intervention, and being in a secure setting as all being vital in facilitating recovery. The stigma associated with having a mental illness *and* being an offender was perceived as impeding recovery and most described recovery as reduction in symptoms and feeling subjectively better. Indeed, those in FMHC are subject to a double bind where they are given two roles - the “patient” and “offender” role – and they straddle both systems not fitting either role or system completely. They are noted to be generally ignored within the “psychiatric survivor movement” (Perlin, 2016). They may be reluctant to voice their perspective due to learned helplessness while in forensic settings (Winick, 2002). It is possible that experiences of feeling unheard and believing that their voice will make no difference perpetuates this silence (Perlin, 2016).

## Experiences of compulsory treatment

The literature regarding the experience of CT in adult mental health and forensic samples is growing. Patients tend to experience mixed feelings regarding CTOs. A Norwegian sample perceiving them as both coercive and supportive (Riley et al., 2014). Patients in New Zealand noted valuing the CTO in giving them access to services, a sense of security (in therapeutic relationships and structure of the clinical team), attributed improved wellbeing to the treatment received under the CTO and feeling that the restrictions did not tend to disproportionately impede their lives (Gibbs et al., 2005). A study of patients’ and carers’ perspectives of CTOs in England identified five themes:

medicalization, playing the game, therapeutic competence and incompetence and amplified control, and forfeiture of credible identity (Gault, 2009). The findings demonstrate that at the outset individuals are reluctant to comply with intervention but do ultimately accept the need for treatment (whether passively or actively); they also emphasise the importance of communication and the benefit of respectful relationships with professionals. Commonly, research on CT has found that perception of negative experiences are mitigated by supportive therapeutic relationships with professionals (Gault, 2009; Gibbs et al., 2005; Ridley & Hunter, 2013; Tan et al., 2010). An early review of Scottish patients experiences of the first 2-3years of the MHCT Act found that; patients did not feel involved in decision-making, a lack of community resources, compulsory care and treatment were experienced as intrinsically unwanted, treatment tended to be from the biomedical model with little psychosocial treatment offered or available (SGSR, 2009). A later study concluded that patients felt that there was improved opportunity for their perspectives to be heard but that the dominant biomedical model had not been impacted by the MHCT Act (Ridley & Hunter, 2013).

A meta-synthesis reviewing all stakeholders' experiences of involuntary treatment orders (ITOs) in adult and forensic services produced several common themes (Goulet et al., 2019). Learning to play the game as an approach, discharge as a substantial quandary for all, finding equilibrium between advocacy and control, the legal process being poorly understood, and a sense of ever-present risk of peril were among some of the main themes generated from the analysis. Questions posed by these findings include whether ITOs promote recovery, whether positive effects of ITOs are related to the intensity of care and treatment and negative effects to its coercive elements, and whether it is ethically justifiable to enforce treatment on those who do not want it when there are not sufficient resources to meet all needs (Geller et al., 2006; Goulet et al., 2019).

## The current study

The aforementioned literature on CT has revealed gaps in the knowledge on whether ITOs promote recovery, whether positive effects of ITOs are related to the intensity of care and treatment and negative effects to its coercive elements (Goulet et al., 2019). It will be important to note how involvement in decision making, compulsion being inherently unwanted, and the availability of psychosocial intervention and community resources (SGSR, 2009; Ridley & Hunter, 2013) may have changed over time and be experienced by participants in the current study. Given the timing of the imminent review of the MHCT Act (Scottish Government, 2019), this provided an opportunity to consider

the implications of this form of legislation. With the increasing use of CT internationally (particularly in the community), there is a growing need to examine individual experiences of this. CORO is among the most restrictive forms of CT, being "without limit of time" and the consequent limitations on individuals liberty. The literature thus far regarding the effectiveness of CTOs has concluded there is little consistent evidence that CTOs reduce readmission or length of inpatient stay (Barnett et al., 2018; Rugkåsa, 2016). Thus, it is important to investigate patients' perspectives of the effects of this form of CT in light of very limited empirical evidence of objective "effectiveness".

The method used here, interpretative phenomenological analysis (IPA), aims to study and encapsulate shared experiences in qualitative data using hermeneutic and phenomenological principles (Smith et al., 2009). The methodology allows for the exploration of new knowledge rather than findings being influenced by predetermined hypotheses, beliefs, traditional methods such as questionnaires or researcher bias (Smith, 2007). IPA therefore offers the optimum method to address the experiences of the novel group under study here. Due to the exploratory nature of the study and methodology no hypotheses were posited, and themes were derived from the data itself.

## Methods

### Design

Semi-structured interviews which focused on experiences of living under CORO were undertaken following an interview schedule (Appendix 9). Interviews were electronically recorded, transcribed and analysed using IPA methodology. Analyses took a "bottom-up" approach; the researcher endeavoured as far as possible to adjourn preconceptions whilst acknowledging the bias inherent in all research.

### Sample and sample identification

Recruitment took place within two Scottish national health service (NHS) Health boards (NHS Grampian and Forth Valley) from within their board-wide FMH services which include low secure inpatient units and community services. RMOs were given a Clinician Information sheet (Appendix 8) and asked to identify patients who met eligibility criteria (e.g. current mental state, risk, capacity to understand the research study and any potential consequences from taking part in it). Clinical psychologists then offered eligible individuals the opportunity to take part in the study and shared Participant Information Sheet (PIS) (Appendix 6) with them. Those who expressed interest in participating to the

clinical psychologists then met with the lead researcher who reviewed the PIS with them. Although a subsequent appointment was offered, all potential participants consented to participate and undertake the interview immediately. Participants were made aware that participation was wholly voluntary and that they could withdraw from the study at any time without providing reason. The consent form (Appendix 7) was then signed by both.

There is no definitive sample size appropriate for IPA methodology (Smith et al., 2009; Smith & Osborn, 2015). However, a sample size of between 4-10 interviews is advised for robust studies such as professional doctorate projects (Smith et al., 2009). This ensures that the research retains the idiographic nature of IPA as large samples may obstruct/hinder successful analysis which requires time, reflection and dialogue. This study aimed to recruit 10-12 participants in order to ensure a suitable number of transcripts was attained and guarantee that multiple perspectives on the underlying phenomena under study were revealed while maintaining detailed analysis. As 11 participants were interviewed and the CORO population is around 290 individuals, this study sampled approximately 3.8% of the entire CORO population.

## Data collection

Data collection comprised semi-structured recorded interviews lasting approximately sixty minutes. Questions were open-ended and followed an interview schedule (Appendix 9) to encourage participants to discuss what was important to them rather than any pre-conceived notions the researcher may have held. The interview schedule was pilot tested on the first three participants and found to be acceptable for use (i.e. questions were understood by participants) without modification for the remaining interviews. Interviews were recorded on an electronic encrypted dictation voice recorder and subsequently transcribed and analysed by the first author. Seventeen patients were invited to take part and eleven participated in the study; none later withdrew.

The interviews took place in NHS settings deemed safe and appropriate from a risk management perspective, low secure unit and day hospitals. No observers were present during the interviews. Brief field notes were made after each interview.

## Analysis

IPA was used to analyse the data for reasons described above. The lead author coded the data. Themes were drawn from the data using a process of initial coding, categorizing and understanding the data with an emphasis on reflexivity and transparency (Elliot et

al., 1999). It is recognised that both quantitative and qualitative research is vulnerable to the personal biases of the researchers and this can affect their interpretation of the data (Cresswell, 1998; Cresswell & Miller, 2000; Strauss & Corbin, 1998). Analyses took an inductive approach; the researcher endeavoured as far as possible to suspend predetermined ideas or views in order not to influence the findings by their "natural attitude" (Husserl, 1931, 1967). Conversely, it is argued that data must be evaluated within its own milieu (Heidegger, [1927], 1962; Satre, [1943], 2003; Merleau-Ponty [1945], 1962). As our conscious experience is always conscious "of something" thus it is defined in relation to something else. The researcher recognised the predispositions resulting from their own experiences (see *Epistemological Stance*) while exploring the narratives and phenomena as they naturally developed (Langdridge, 2007). The aim being that the analysis was tempered by reflexivity and remained true to the data.

Though there is no stipulated method of conducting IPA, the analysis here undertook the stages noted by Smith and colleagues (2009). This included: reading and re-reading; initial coding; developing emergent themes; looking for connections across emergent themes; replicating these steps for the next transcript; looking for patterns across transcripts. The transcripts were initially coded and analysed using "comment" capabilities in Microsoft Word software.

Themes were returned and discussed with two participants. Both participants agreed with the themes that the lead researcher had derived from their transcripts and reflected further on these.

## Ethical considerations

The study was approved by NHS North of Scotland Research Ethics Committee 2 (Appendix 10). Recordings were deleted following transcription, and transcripts excluded identifiable data.

## Epistemological stance

The lead researcher was a white, Scottish female. The participants were largely males of white Scottish ethnicity, who were detained under the MHCT Act either as inpatient residents in low secure units or CD'd to the community. Therefore, the researcher held a position of relative power. The researcher was not given any information regarding the participants before they met, thus lessening the power imbalance and aiding the researcher in remaining reflexive (in addition to ongoing supervision encouraging open-

mindedness towards the data). Given the method of IPA, the researchers sense making of the participants experience has overall dominance.

## Results

Four superordinate themes were generated from the analysis: *(1) How did I end up here? (2) Impact: Power, Punishment and Protection (3) Surviving and Adapting (4) Recovery.* Table 1 exhibits the superordinate and subordinate themes and demonstrates in which transcripts the themes were found.

Table 1. Superordinate and subordinate themes across participant interviews (shaded cells indicate presence of theme)

| | Innes | Lennox CD | Lewis | Harris | Caelan CD | Archie | Donald CD | Magnus CD | Brodie CD | Bruce | Tom CD | Prevalence |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **How did I end up here?** | | | | | | | | | | | | |
| Making sense of mental illness and link to offending: "I wasn't in my right mind" | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | 100% |
| Realising the gravity of CORO | ■ | | | | | | ■ | | ■ | ■ | ■ | 45.5% |
| **Impact: Power, punishment and protection** | | | | | | | | | | | | |
| Always under watch | | ■ | ■ | ■ | | | | | ■ | ■ | ■ | 54.5% |
| Your life's out of your hands | | ■ | ■ | | ■ | ■ | | | ■ | ■ | ■ | 63.6% |
| Found guilty of having a mental illness | ■ | | ■ | | ■ | | | ■ | | ■ | ■ | 54.5% |
| On being a chaperoned adult | | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | ■ | 72.7% |
| Protection and safety | | ■ | | | | ■ | ■ | ■ | | | | 36.4% |
| **Adapting and surviving** | | | | | | | | | | | | |
| Exercising the power and choices you do have | | | ■ | | ■ | | | ■ | | ■ | ■ | 45.5% |
| Passive resistance | ■ | | ■ | ■ | ■ | | | | | ■ | ■ | 54.5% |
| Active acceptance | | | | | | ■ | ■ | ■ | ■ | | | 36.4% |
| Avoidance and shifting focus | | ■ | ■ | | | | | ■ | | ■ | | 36.4% |
| **Recovery** | | | | | | | | | | | | |
| Reciprocity in relationships | | | | | ■ | ■ | ■ | ■ | | ■ | ■ | 54.5% |
| Finding the right medication | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | 63.6% |
| Having a purpose: Psychosocial treatments | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | 72.7% |
| Self-disclosure; Navigating new relationships | | ■ | ■ | ■ | | | | ■ | ■ | | ■ | 54.5% |

N.B. To preserve anonymity, the gender of individual participants is not reported specifically, all names have been changed and all participants are referred to as male due to the sample being from a small and identifiable population. Conditionally discharged: CD.

## How did I end up here?

All participants described the sense they had tried to make out of what led them into FMHC and being under CORO. This included attempts to make links between mental illness and offending, often this evoked a sense of sadness, regret, confusion or humour regarding their previous actions. Some participants reflected on being unaware at the time of the journey that lay in front of them, the gravity of being under CORO initially and coming to this realisation later. Overall, the findings here reflect that participants sense of self was altered by coming in to FMHC and for some by being placed on CORO itself.

### *Making sense of mental illness and its link to offending: "I wasn't in my right mind"*

For some, this process of making sense was ongoing and they experienced ambivalence regarding this. Tom discussed holding contrasting paradigms of mental illness and developing insight over time. While grappling with uncertainty whether he experiences mental illness or not, he tried to make sense of where psychological and social factors fitted in with the dominant biomedical model of mental illness:

> *Tom: I'm only really finding out about my mental illness now that I've become more well. At the time I never thought I had a mental illness but now I am wondering more about it. […] I do understand that things have been a bit muddled up in my head before so I have to say that yeah there has been a mental disorder of some kind […] My alternative hypothesis would be that I was… I don't really want to go into my past situations and things but in brief I would say that I had been messed about with by people and that would be the reason that I was thinking not 100%. … That has been inflicted upon me rather than it being some sort of malfunction or illness of the mind.*

Having experienced mental illness and committed an interpersonally threatening act during a period of acute mental ill health some were able to reflect that the risk they posed to others at the beginning on their journey had been fundamental in their move to secure care:

> *Donald: I committed a serious assault and now that I realise why… I was sent to [hospital] cause I was dangerous.*
>
> *Magnus: Yeah dangerous when I was extremely unwell – I understand that and this is why I have the CORO on me cause when I was unwell I was a danger to myself and the public.*

Recognition of distress, reduced functioning in the context of acute mental ill-health and the point of entry into FMHC being a low point in life was noted frequently in the transcripts:

*Innes: My head wasn't in the right place, it wasn't… and I wasn't sleeping and I wasn't eating so… I thought I saw Jesus as well so it was y'know… [sighs]*

*Lewis: …when I was first detained under a CORO. Things weren't very good at that point at all. I had just tried to kill myself, things were bad for me at that time…*

Magnus reflected on the impact of realising how being mentally unwell and offending were linked, initially causing him to feel disheartened then refocusing this strength of feeling into recovery. He described the sense of negativity in being perceived by others as "dangerous" but how he used this to motivate himself to prove to others that he was "good" and in recovery:

*Magnus: I was adamant to prove to everybody that I'm not this dangerous person that because I was unwell… I'm in recovery and I'm reading this when I'm in recovery it was really deflating but like I said I just fired it in the opposite direction – nope, I'm gonna prove it, I'm gonna prove that it's not the case. So it had the reverse effect on me "Well let's do this, let's prove the point".*

### *Realising the gravity of CORO*

Some participants described not having a clear understanding of the legal processes early on in their journey. Once more familiar with services and realising that the order was "without limit of time" some indicated becoming aware of the gravity of CORO on their lives:

*Brodie: At the time I didn't realise how serious it [CORO] was. When I got put on it. I thought oh it's just another section I'm no bothered but after I been on it for years that's when I started to realise how serious it was.*

It appeared that some did not understand the basis of their legal status:

*Bruce: Yeah, they're using the Mental Health Act to detain me. I don't really understand the Mental Health Act.*

While some felt that CORO was explained to them in some capacity, they experienced the explanation as inadequate or inaccessible:

*Tom: It [CORO] was not [fully explained]. Completely. Definitely not… Well it wasn't really explained to me at the time. I was just told that the government will have input into my care and that will be the only difference.*

Some reflected that their sense of self was disrupted in a negative way when focusing on the gravity of being detained on this order:

*Caelan: It does actually make you feel quite bad to know that you are criminally detained.*

## Impact: Power, punishment and protection

This superordinate theme concerns how participants perceive the impact of living under CORO and how they perceived power to operate within the systems. Some described experiencing systems and staff as exercising power over them in a punitive manner by monitoring, supervising, and taking decisions over their life on their behalf. Some voiced the double stigma they experienced in systems and society at large in their holding of disempowered dual roles ("offender" and "mentally ill") in society. Conversely, some described experiencing power in the hands of systems and professionals in a positive way; the CORO perceived as protective and allowing them access to services, helpful treatments and beneficial therapeutic relationships.

### *Always under watch*

In the context of being under FMHC where individuals are continually monitored and assessed some discussed the sense of feeling constantly under watch. Some noted at times internalising this to become their own "self-monitors" and the irritation this caused having to constantly be on self-guard:

*Brodie: It's quite annoying, it's quite annoying. Cause I've got to watch what I say all the time and what I do and my actions and yknow I've been doing that for 16 years now. It's a pain… It's like pressure all the time Vivienne. Aye it is aye, knowing that you're on that section.*

Some described struggling to understand the rationale for being monitored and this constant external observation disrupting their sense of self. They became the "watched" and this caused them to become exasperated with the "watchers":

*Lennox: I was on 24 hour watch and… I didn't like that… I hated lying in my bed trying to sleep and somebody sitting watching me […] And I mean I couldn't understand why after a certain time why didn't they just go away but no they had to had to keep an eye on me. You're followed everywhere.*

Harris explained how he was supervised in his daily activities and how he took this to mean he was set apart from others. The people who can do what they want and those who cannot; a sense of being "othered":

*Harris: Well a CORO's a lot is definitely a lot better, a lot worse than a normal sorta what would call it informal. You get sorta informal patients where they can do what they want. Where I live there's a corner shop up the road now I can't go by myself, I've got to go with a member of staff.*

Some described a sense of being "othered" or stigmatised, however, not internalising this message. Lewis remained robust in his assertions that his behaviour was in fact "normal". He appeared to perceive that his behaviour was pathologized, through a "forensic lens", when in any other life context it may have been interpreted as "normal":

*Lewis: …what they say is "oh well you don't talk about your mental health much" but that doesn't mean that what you're talking about is superficial just because you're not talking about every little nuance of your mental health or your mental outlook or whatever. My conversations are no more superficial than anybody else's. I think they used to use that word to mean well yeah he's not all always talking about his mental health.*

The system exists to support individuals however at times the response of the system causes patients to feel stigmatised. Perhaps, the system expects a level of psychological mindedness in patients which would not be expected in any other walk of life. If this ability to reflect on inner thoughts and feelings is not readily and outwardly expressed by patients to staff then at times the absence of this information is perceived as problematic, possibly threatening and hinders progress.

### *Your life's out of your own hands*

Some reflected on the lack of control they had and how others command significant power over their lives. They voiced how being in this vulnerable position affected their emotional world and sometimes led to feeling powerless, despondent, frustrated:

*Bruce: I really, I've no control.*

*Caelan: It's just a feeling… Somebody else has got the last say in what I can do yknow.*

*Lewis: Yeah it's not a good feeling that… a locum psychiatrist can have so much power over you or how much time you spend in hospital and such like. […] found it a bit depressing the thought that your life's out of your hands. Being out of your own hands so much.*

*Tom: The patients have no power and the staff have a lot of power over the patients.*

Some reflected feeling that the only reasonable option in the situation was to trust staff but that was an exposing position to be in, particularly when trusting others is already a core difficulty:

> *Archie: I'm not a very trusting person… that's not my kinda character yknow. Mostly cause I've had it a bit rough in my life yknow so I've always been doing things myself and I've been put in a position where the only real option is to trust the staff is quite yknow worrying sometimes.*

Archie discussed how a seemingly small action can result in major consequences (i.e. recall to hospital, loss of passes, or being moved to higher security). This reflected a sense of being punished and that their recovery was being put back a step:

> *Caelan: It would only take one stupid move and it would all just get washed away and I'd be back in hospital again.*

The delicate tight rope walked day to day, the ever-present sense that something could go wrong at any time (i.e. recalled back to hospital at any time) appeared to result in a lack of a sense of permanency in life for some:

> *Lewis: I've had the 6 admissions now and yeah nothing to stop there being a 7th maybe. […] Things are going alright at the moment but yknow doesn't necessarily stay that way.*

> *Caelan: I feel like everything that I've got is just, is just on loan to me… I don't want to go back into hospital.*

Patients face a continual balancing act in that they must adequately and actively divulge their inner psychological world to staff however in doing so they risk saying the "wrong thing". The very challenging task of finding and maintaining the balance makes it difficult for patients to succeed as the "correct path" to succeeding appears to be narrow.

> *Archie: I had all these off grounds passes and then one day one of the doctors asked me a question and I was sitting there thinking it was best for me to answer honestly. So I answered honestly and that was how I did things, moving back a little bit […] It's just that, that kinda threw a bit of a spanner in the works... Yeah it was a little bit like I was being punished for being honest. If I'd kept my mouth shut things probably would've gone fine, yeah.*

### *Found guilty of having a mental illness*

Some described a sense of injustice and perceived their detention as a form of punishment for something over which they had little control (severe mental illness). Some discussed feeling

they had lost basic rights (e.g. being able to defend themselves, loss of right to a "normal" life) which again spoke to feelings of powerlessness:

> *Bruce: I'm stuck without limit of time. I've never had a trial. If I was found guilty by a jury I'd accept it. Some people if they're put away without limit of time it's at the High Court. It goes on for 3 months. Everyday. Day after day. I never had a trial. I never had a trial.*
>
> *: Human rights went out the window.*
>
> *Tom: I don't think I'd ever plead mentally unwell again… because I want the chance to be able to defend myself and I like to have my rights preserved and being on a CORO takes your rights even further away from you than being on a CTO does.*

Some could not help but compare their experience to others in the same environment but who were under different orders. Magnus appeared to make sense of this by viewing himself as disproportionately disadvantaged:

> *Magnus: When I was charged with the assault and robbery - compared to another patient who [committed a violent assault leading to serious injury[4]] who had more freedoms in [hospital] than I ever had... We were on completely different orders but… the comparison of index offence, there was quite a huge difference. I could see them getting all these freedoms and going out for 3,4,5 hours a day. Going out in the morning and not coming back till evening and I'm like "Oh okaaay".*

Some voiced that they felt the conditions of CORO were not proportionate to their offence; conveying that felt they were being doubly penalised for their crime. Often, citing that in the prison system they would have "served" less time. This may indicate that CORO is seen by some as a "punishment" order or "sentence" rather than it's intended role a form compulsory care and treatment without a punitive element. For some this may reflect a lack of understanding of the system or a sense of injustice:

> *Tom: If I went to prison for the crime I had committed then I would have spent about a year in prison maximum […] then I would've been out free and been able to do whatever I wanted. But because I am with the mental health system I got 7 and a half years [in hospital] and a year on from there they're still on at me… so.*
>
> *Innes: A life sentence. It's felt like that y'know… so I think if I was sent to prison it would have been less and I would have been out.*

[4] Details of offence anonymised in order to preserve anonymity.

Tom appeared to experience the CORO restrictions as being disproportionate to his perception of the level of harm/risk he posed towards others therefore leading him to see the system as punitive:

> *Tom: I think it's way over the top. For somebody that's been considered well for the past three years and considered not a danger to himself or others I think I should be given a lot more freedoms than a CORO allows me… it's like if you've got a mental illness you are found guilty of having a mental illness and are locked up for it… And the penalty for that is normally like a year and a half in hospital.*

Lewis drew comparisons between the incongruity of his actions during his index offence (due to mental illness) compared to who he is when well and others who present with consistently anti-social, aggressive attitudes and behaviours. He considers that those who offend without having a major mental illness are treated with greater leniency. He appears to understand the rationale for CORO comprehensively however holds this in mind simultaneously to his sense of frustration and injustice:

> *Lewis: The guy that maybe I don't know he's just a nasty guy, and beats his wife up every 3 months, or every 6 weeks or something like that or does it every Saturday night the most he's gonna get is 6 months in jail and that's it. When he's out he's out. Whereas I've done 4 and half years locked up for something that's totally out of character for me. For something that was totally out of character for me. I realise the arguments for keeping me locked up and what not… but it doesn't seem fair in comparison to somebody, these guys who're assaulting their wives every Saturday night.*

Some described the negative effect being placed on CORO had on their sense of self and who they now believed society perceived them to be (e.g. unpredictable, less than human, unworthy). Often, they now understood society's perception of them as being a "second class citizen" or not a "real" person:

> *Lewis: It makes you less of a human being in a way.*
>
> *Tom: I would say that ever since I've been in the mental health system my voice hasn't been heard… I tried to get my message across when I first entered the mental health system and it was like nobody was listening at all. They were just deploying rules down upon me for having a mental illness.*

The repetition of phrase below speaks to the strength of negative feeling Caelan has towards his CORO and the message he perceives it gives society about who he is; undeserving of living a "real" life:

> *Caelan: I hate it. I hate the section. I just hate it. It's a weight on me the whole time. Mentally yknow. It's like it's always on the back of my mind yknow like I'm no a real person, I'll never feel like a real person. […] I met a lot of people who have got discharges who have murdered people. I never murdered anybody but one of the things about this section is that you dinna feel that you have the right to say that. I don't feel you have the right to actually say that "I wanna live" [sighs and laughs]… People say… "you've got a bee in yer bonnet" yknow.*

Additionally, Caelan perceived that staff and society saw him as untrustworthy and high-risk thus not permitted to experiment in life as one normally would:

> *Caelan: You never get to the point where people are actually saying "Right, this person actually knows now. Knows his limits now yknow". I've never had a chance to actually explore my limits yknow.*

In contrast, Magnus explained that although he held nominal membership to the CORO group he never internalised the negative "identity" that society may have ascribed him:

> *Magnus: I would've been in a group of patients in each hospital, in [high secure], in [medium secure], in [low secure]. Yknow you come under the "Oh are you a CORO patient?" "Yeah I'm a CORO patient" "You a CORO patient?" "Yeah" so I came under that identity but I never, I never took that identify on like personally if that makes sense?... I'm not gonna try and let that burden me and get me down and stuff.*

This may in part underly Magnus's experiencing of CORO as protective (see below). For some, the label of mental illness means that they feel their voice is not heard or taken seriously:

> *Tom: It feels very unfair. It feels like your voice isn't heard. I was always used to my voice being really heard and I could say things and be outgoing and speak to people… before I had the mental illness. Before I was under a CTO. I could speak out and be heard and a lot of the time I'd get what I want. Before the mental health system, in school and general life. Various different aspects of it.*

### *On being a chaperoned adult*

Some discussed the restrictions they live under regarding who they can meet, consort with and which private residences they can enter. For some, being a chaperoned adult resulted in feelings of loneliness and difficulties in meeting basic human needs for physical and emotional connection with others. Some experienced this as challenging, restrictive and frustrating:

*Lewis: So I think I'm allowed to bump into people and speak but I think if I want to go round and see him or her they'd have to send a social worker round… And that's really heavy. That's that that… yknow that impacts, it's gonna impact on your relationships.*

*Archie: So I don't have the permissions to go to somebody else house which is quite annoying cause that's' been the one time when the CORO has been quite restrictive.*

Some discussed the difficulties encountered in developing intimate relationships where their RMO is required to meet the new prospective partner within a short time of the patient meeting the partner. Lewis reflected that the CORO itself as being an off-putting barrier for developing relationships:

*Lewis: … before you know it they had made her come in and see them and tell them everything about my offence and what not and that's, that has a fair impact. […] they [new partner] would have to be pretty sure I can imagine it must happen lots of times that people are just put off by it. I can totally see why people would be put off by it. The fact that you're on a CORO.*

Some voiced that although technically they could develop intimate relationships with permission of their RMO, they felt that being on a CORO and the steps a new prospective partner would have to go through inhibited this process entirely and made it an unrealistic prospect altogether:

*Harris: So… I don't even try to think about meeting a girlfriend. Cause what's the point? I can't say "Oh I can't come out tomorrow cause it's not in my planner" [laughs]… They'd be like "what planner? What you on about?"*

*Brodie: I've got a carer at half 10 in the morning. Yknow and what is she [potential partner] going to do? Sit there with the two of us talking? Can't really do it.*

Tom voiced the loss of old friendships he believed due to the restrictions imposed on where he could travel to:

*Tom: Well I don't get to see my friends when I'm on a CORO so obviously there's no relationship there. Whereas if I was on a CTO I'd just go down and see them… well old friendships are gone because of the CORO.*

Lewis was cognizant that restrictions on intimate relationships existed for some individuals for clinically justified reasons which perhaps mediated his perception of these as reasonable and founded compared to others who experienced these restrictions as punitive. He was able to mentalise from the other persons perspective why this would be important:

*Lewis: I suppose if you reverse the thing and I'd met somebody yknow who'd… I dunno say had a history of murdering their, their… boyfriends had murdered two boyfriends, or even one I suppose you kinda think oh yeah it wouldn't be such a bad thing if I was to find out about that. So I suppose I can see it from that point of view... totally see the point. Really see the point that if somebody's got a history of offending it's only fair that a potential victim should find out. So I totally agree with it.*

### *Protection and safety*

An interesting juxtaposition arose in the data where some appeared to view CORO as a protective mechanism – "a safety net" – in contrast to the who experienced CORO as punitive. It appears this subgroup understood the order differently; viewing it as a channel through which they could access helpful treatments, supportive therapeutic relationships and approaching it with an assumption of trust rather than suspicion. This may be easier for those who had more positive experiences with authorities and caregivers early in life and more difficult for those who had difficult or traumatic experiences of care. This may also be mediated by having a more comprehensive understanding of why they have been placed on CORO.

Magnus and Donald appeared to value the availability of care, reassurance and supportive relationships with staff which aided them in experiencing CORO as protective:

*Magnus: Having a severe mental health condition… experiencing mania… it's quite a relief to have a care team behind you. It's quite positive and it gives me motivation to… move through and to get on with things and to keep going and to make the right decisions […] I take their advice. So it's always, it's like having a second check in a way.*

*Donald: I'm quite happy with the level of care that I receive and the section it doesn't really affect me.*

For Lennox, he experienced the CORO as being in place to protect him (more so than for the protection of other people) which allowed him to experience the CORO as a positive intervention:

*Lennox: I think it's more about my protection than other peoples' protection.*

For Archie, viewing staff as supportive (rather than punitive) thus allowing him to be able to trust in the mental health system was fundamental in his experiencing CORO as positive and protective:

*Archie: So I just kinda try and trust in the system will work and the staff will work stuff out cause that's their duty as part of their job and stuff… Just because the mental health*

*systems there to help to get me healthy yknow. I know that the mental health system is doing it's very best to get me back out the door and on with my life.*

For some, the power of the system in making choices in your life was in fact understood as positive and protective. Lennox reflected how his unintentional breaking of a restriction (meeting a female in private) initially resulted in low mood but that the response of the system in this situation was eventually a positive thing, ensuring that a greater issue was prevented from occurring later:

*Lennox: I was back at square one… Oh it was terrible yeah. Depression came back again […] it was a lesson learnt because then I was really clear what I could do and what I couldn't do because the chances are I might have got out and invited somebody round to my house without thinking and it could've been worse.*

## Surviving and adapting

Participants described a range of methods and coping styles they developed in order to navigate and cope with the unusual situation they found themselves in. Though subthemes were disparate across transcripts (representing subgroups of coping style), these themes all appeared to share similar functions in that they allowed participants to continue living day to day, tolerate challenging emotions and/or restoring a sense of power/agency (however small) in their lives.

### *Exercising the power and choices you do have*

Some participants described coping with the lack of control and certainty over their own lives by exercising powers (thereby, taking back some control) they have available to them through legitimate means such as tribunals and advance statements:

*Lewis: In 2010 I did that [challenged the status quo]… In that sense that was the mental health act, that was the tribunal system that allowed me to get out [of hospital]… yeah advance statements are just you need to make it when you're in your right mind. The idea being that when you're thinking clearly you can list medications or treatments that you don't want and medications and treatments that you're happy to have… in my experience doctors have actually tended to take my advance statement into account.*

*Magnus: So when I was going for conditional discharge I put in a request that I don't want to do planners anymore and they said "yeah okay, no problem" and that came from the Scottish Government as well and I was like "Yesssss!!! Somebody's listening!"*

This may reflect for these participants some sense of power gained through increased understanding of the legislation, system and how to utilise this. Other participants described how they may have attempted to seek power from staff or the system in somewhat proscribed ways. Caelan described how he was aware he was likely to be transferred to a higher level of security so he exercised "control" or a "last show of freedom" and absconded from the low secure ward:

> *Caelan: …so I climbed out a window. Went away got drunk, stole [unclear] and came back the next day. Came back and I knew I was going to [higher security hospital]. Came back and within about 10 hours I was in [higher security hospital].*

Tom described his attempts to gain a small sense of power control by playing with the flexibility of the rules or verbalising displeasure in order to address the power imbalance he so keenly felt. This could be considered as a form of active resistance:

> *Tom: This doctor would only listen to you when he was hearing what he wanted to hear or you said "I want out" and his answer would be "no" to that straight away and that I thought was just completely wrong. I would say things to him to wind him up and the staff would be like "Doctor, listen to him! Listen to him!"… and they'd be like "LISTEN to him! He's winding you up!" […] I was like "well I've still got ten minutes to go out" and he [nurse] was like "you'll be twenty minutes" and I was like "ten minutes" and he said "right I'll let you out". I was twenty minutes and then I came back in and he said "I knew you'd do that" and I said "yeah cause I CAN do that. I CAN do that. There's no rule against me doing that." And he was like "I've got rules" and I was like "whatever mate" and walked off. [laughs]*

### *Passive resistance*

This subgroup appear to oppose the system (in their minds) while behaviourally complying with it in order to move forward. This may be mediated by the assumptions that the system is punitive, they are stigmatised by society for their dual roles and that they have little agency and power over their lives so have little choice other than to comply.

The below excerpt illustrates the significance for Bruce in "conforming" to staff expectations of behaviour to garner their approval in order to progress. Bruce described concealing anger or behaviour that could be interpreted as "aggressive" by staff in order to keep progressing:

> *Bruce: I never talk back to any of them or get angry at them. Even if they try to anger me, they're looking for a reason to give you medication or what… Never talk back to staff, never get angry, never make demands of them… Well I just bite my tongue with*

*everybody. I don't talk back or get angry or that I just stay in my room. I'm a model patient I can tell you.*

The excerpt below demonstrates how this subgroup may comply behaviourally with treatment (e.g. take medication) despite beliefs that they do not require this perhaps reflecting limited insight:

*Bruce: I take my medication although I've never needed it… It's terrible… It's really, really hard for me.*

Harris described the process of modifying his behaviour so it was "acceptable" to others – from active to passive resistance - as something that took time to develop over many years:

*Harris: I've learned over the years Vivienne, well how to be a normal person, not to cause bother… there was a doctor she told me "You've been a pain in the arse ever since you come here"… I used to smoke dope and everything on the ward [chuckles] oh it was hellish. Looking back – aye I was crazy.*

Bruce discussed the emotional pain he experienced in perceiving little other choice but to comply and perhaps reflecting on the loss of an alternative life he may have had had he not been in FMHC:

*Bruce: … here I am 30 years later. Twenty odd years later and still I'm here and I am a "model patient". […] Well sometimes you feel like throwing yourself to the walls ay. You've just got to cope with it. You've been given that and you've just got to deal with it but you do feel like throwing yourself at the walls at times. It's really, really hard honestly.*

Innes described how he gained the acceptance of staff by refraining from "acting out":

*Innes: Yeah I get on okay with the staff there's been no problems. I don't kick off, I don't shout and scream y'know.*

Lewis described agreeing ostensibly with staff regarding "symptoms" of mental illness whilst holding his own personal formulation of what these experiences may be (his faith):

*Lewis: I can call it a delusion when I'm speaking to the doctors just to make it easier for everybody but if you thought it was a delusion you wouldn't have the belief if you yourself thought it was a delusion. So yeah I'm well aware that for everybody except me that is part of my mental health problem… I know that the belief that you're the second coming of Christ I realise that almost nobody else will accept that.*

Lewis appeared to have decided to “conform” to the system and agree outwardly that his experiences were symptoms of mental illness in order to progress in the system whilst holding his own private view of these experiences. Tom discussed how he navigated a complex double bind when receiving opposing messages from Multi Agency Public Protection Arrangements (MAPPA), health and legal professionals and complied with “the rules” in order to progress through the system (though personally disagreeing with them):

> *Tom: I talked to a lawyer and he said that I don’t have to live by them [rules made by MAPPA] but my doctor says don’t trust the lawyer. So as far as I can see MAPPA can sorta like dictate what I do, where I live, what time I’m out at and things like that. They do things like that and I don’t have them on my restrictions, but they are. A few times I’ve said “I don’t have to abide by this” and they’re like well technically you don’t but… everybody has said that technically I don’t but if I don’t it’s a black mark against me sorta thing and it would ruin an untarnished record. So I want to keep it that way cause I’ve got a Tribunal coming up in three months and I would like to have my untarnished record kept clean for that.*

Harris discussed having to obtain staff permission before he can meet friends in town, how this has gradually become an automatic response, although he still disagrees with it on some level:

> *Harris: It’s a bit of a pain but like I said I’ve been doing it so long that I do it automatically. I know what I can do, I know what I can’t do… I’d like to able to go about as I please without having to ask let’s put it that way. Without having to ask: “Can I go here? Can I go there? Can I see him? Can I see her?”. It’s just not on ysee, it’s not on but cause I’m that used to it [sighs] it doesn’t bother me yknow it’s just the situation Vivienne I’ve had to accept it.*

### *Active acceptance*

Another subgroup of patients appeared to describe conforming to the system however in contrast their compliance appeared to be active and based on assumptions that CORO offered positive advantages. For example beliefs that: CORO provides access to helpful treatment, that staff have supportive intentions, active engagement is fundamental for recovery, personal goals will still be achieved though this may take longer and/or desire to prove to society that they are ”good”. Archie described beliefs that staff had appropriate knowledge training, and experience to aid his progression:

> *Archie: I’ve kinda been complying with the doctors recommendations because… the doctors the ones who’s been trained in dealing with psychosis and symptoms like and*

*I'm just hoping that she manages to get the job done so I can be like "everything's fine - gonna move forward with my life".*

Donald alluded to beliefs that following the rules and actively engaging is the best course of action for his own wellbeing:

*Donald: I try to follow everything… Myself, personally I've never been restrained. I followed the book if that's the right word to use… I think that's what Dr [name] says: "I wish my patients were all like you!"… Model patient aye!*

Magnus described how he believed being fully invested in the care and treatment had been crucial in his successful progression to CD:

*Magnus: Someone had said to me "you know if you really look back Magnus, for being a CORO patient you've flown through the system" and I said "I know but I've really worked hard for it" dyou know what I mean? I committed to everything, I did all the intervention therapies, I participated in everything that I could and I adhered to all the planners and stuff…*

Archie discussed active compliance based on assumptions that his goals will be attained eventually:

*Archie: I mean the thing with the CORO is if you kinda comply and go with the flow and stuff you still get all the stuff that you're wanting to get like […] I'll be able to get a new laptop, a new phone. When I get back to rehab I'll be able to go to the cinema and stuff, with people I've made friends with while I've been in hospital.*

Magnus reflected on his intrinsic motivation to demonstrate to the world that he was fundamentally "good", not "dangerous" and how this helped him to actively engage under CORO:

*Magnus: I zipped through the system but that's because I was motivated to prove to people that I was not this dangerous person and was not a risk to the public… it was a motivational factor for me cause I thought "I'm not getting anywhere till I'm better so I've got to prove. Prove to everybody that I'm committed, I'm following the ethos of being recovery-based focussed, I'm taking ownership of my mental health".*

### *Avoidance and shifting focus*

Some participants described coping with living in a situation out with their control by shifting their focus to things they could control (which gave them a sense of agency over their own lives) or shifting focus away from a restricted life by "sealing over" and engaging in mental

avoidance. This coping method may be based for some on (perhaps unconscious) assumptions that confronting the reality of the situation may be too painful. Lennox described an avoidant "sealing over" approach towards how he would manage situations with people he knew before he became unwell and committed his index offence:

> *Lennox: You walk up the street and you bump into people every time but now I'd never see them so… I don't think they've even bothered to find out where I am… It doesn't bother me. No, it doesn't because yknow I think if I was to bump into one or two of them I think they'd want a lot of questions answered and I don't know what their feelings are towards me yknow.*

Bruce, too, described an avoidant coping style in which he used self-isolation in order to maintain a feeling of safety:

> *Bruce: I'm quite happy 20 hours in my room as long as I get peace but losing your freedom all these years. That's the worst thing ever... Just shut myself in my room… I've cut ties with everyone. As I say the social work, the Mental Health Officer, 4 church friends, ay advocacy. It's hard to recall it now. I just wanted a quieter life yknow. If I stayed away from them I'd have a quiet life ay.*

Lewis voiced that staying cognitively in the present helped him in to cope with the reality of being detained indefinitely under CORO:

> *Lewis: It's better just to live in the present moment. Yeah looking ahead can be a bit depressing at times… About half the time for the last 22 years I've been in hospital… I know that there's no point. There's no point in living in the future and always thinking about "I wanna do this when I get out, I'll do that when I get out".*

Similarly, Magnus described focusing on improving himself rather than focusing on the outward situation:

> *Magnus: The up rest and the upheaval with, that was at the State Hospital but I soon forgot about it honestly and thought focus on other things, focus on yourself and I did…*

Lewis described how shifting his focus to his faith aided him in coping with the reality of his situation:

> *Lewis: What I'm really thinking about not just for the future but for the present, by far the most important thing for me is my faith… ehmm I suppose I'm quite unsure about the future, very unsure about the future, there's all sorts of question marks about the future but as long as I've got my faith I'm not scared of anything.*

## Recovery

The fourth superordinate theme identified concerned what participants experienced as valuable in their recovery, what helped them heal and connect with their lives and others moving forward into the future.

### *Reciprocity in relationships*

Some participants noted how in navigating their relationships with staff they had attributed part of their success to approaching interactions in a reciprocal manner. Those who endorsed this theme presented with insight into the fact that reciprocity in interactions provided both parties with positive reinforcement, staff were more likely to build trust in them and trust in professionals appeared to mediate this theme being endorsed or not:

> *Archie: There was a time it was my birthday they got me a cake and stuff. So they're always really considerate and make things a lot easier being in hospital yknow but I think that's mostly because I've been so accommodating with the staff yknow. You give out and you get back yknow? …Things have been, they've been a lot better than they could have been yknow and it's probably to a certain extent due to my attitude and things.*

Some discussed how trusting the staff (thereby earning staffs trust in them) and at times desiring staff's approval aided them in progressing:

> *Donald: Trust? … If I wanted to ask, put in a request to Dr [name]… she'll say "Okay" but I think I've never gave her problems. Never, never. I've never sprung her a surprise at any of the CPA meetings […] I don't want to let Dr [name] down like.*

> *Magnus: Eventually when I was in the [medium secure unit] yknow I did get a lot of passes but it took a lot of time to build that up. I dunno whether it was just building the trust up with the staff which is understandable because they need to have an element of trust before they can let you out in [local city] for four hours.*

Bruce recognised how his actions impact on staffs emotional wellbeing and the importance of his role in contributing to regulating their wellbeing:

> *Bruce: I mean you've got to try and keep them having decent feelings inside instead of getting them angry and that.*

Some spoke of therapeutic bonds being built with particular members of staff and the positive impact this had on them and how they were affected by the loss or temporary absence of these relationships:

*Donald: I became friendly with a member of staff there… we got on great… he died like… I was upset with that yknow… When Bob was alive, god bless him. He would take me down to do ASDAs to do my shopping for the week aye. My keyworker, he was good yknow… It made life easier.*

*Brodie: Sometimes if I'm in the house on my own in the morning I get a bit lonely a wee bit but sometimes I look forward to my carer coming to my house.*

### *Finding the right medication*

Another aspect of healing frequently discussed by participants was the journey they went on with their doctors regarding finding the right medication(s) at tolerable dosages. They reflected on disadvantages of being on medication and dosages they found difficult to tolerate which at times engendered feelings of powerlessness. Whilst simultaneously identifying the positive experiences (sometimes life-changing) when they found medications that improved their distress and symptoms.

Some participants discussed the challenging physical and emotional impact of medication they struggled to tolerate:

*Lennox: It was just this one particular one, I think it was quite new on the market. They decided to try it out and as I say it had a terrible effect on me.*

*Lewis: Some of this stuff really ruins your life... some of the stuff I've been on. For example, haloperidol it's difficult to explain it's just is a pill and you think it wouldn't make that much difference to you but it makes a huge difference to you. It wiped out my personality altogether, I had no interest, I had no quality of life on that drug.*

Lewis discussed his experience of negotiation with different doctors and moving between a sense of powerlessness regarding a doctors opinion and attempts to gain a voice in the dynamic by using advance statements:

*Lewis: Oh yeah, it depends a lot on the doctor. Some doctors don't much negotiate with you… Yknow I've been prescribed diazepam to help with the side effects and really what I wanted was to get off the medication to get on to medication I could deal with […] medication I could tolerate… I mean I've got an advance statement and I've listed some of the meds I don't want to take and some of the meds that I can take.*

Some reflected on how the power imbalance was only present when patient and doctor disagreed on medication and appeared to fade when tolerable medications for the patient were found:

*Lewis: Well it's easy if you're on meds you can tolerate and difficult if you're on meds you can't tolerate.*

*Lennox: Well when they get the right ones it's been okay.*

Archie also described a sense of powerlessness being early in his medication journey with his doctor:

*Archie: So I'm kinda in a state of limbo at the moment. Waiting for my doctors to get me on the right medications. So it can be quite challenging sometimes...*

Some participants discussed the positive experiences they have had when finding medications tolerable to them which reduced distressing symptoms or restored functioning such as sleep:

*Harris: They gave me an injection called modecate… It's really strong… I got it one afternoon and woke up the next day and thought "strange? No voices. No paranoia". It took it away.*

*Caelan: Was on 525 [mg] of clozapine. On 425 mg now. I'm a lot quicker, less sedated than I was…Oh a lot better. A lot better. Physically especially. I take it [clozapine] every night. It does knock me out. For an hour and a half it feels really nice and then it feels really heavy and then I fall asleep and I forget all about it till I wake up the next day.*

*Brodie: I got put on clozapine in 2003 and it's helped quite a lot […] as soon as I got put on the clozapine it's made me a lot more weller.*

It may be easier for some to accept the need for lifelong medication if their personal goals (managing their condition) align with staffs/services goals for them:

*Magnus: At the end of the day I'll be on medication for the rest of my life. It's about helping me manage the condition.*

Donald discussed the positive life-changing effects that the correct medication had for him. The positive effects of medication and comparisons to poor quality of life before for some may work to encourage compliance:

*Donald: I had nae quality of life. None whatsoever. No quality of life. Till I went on clozapine and that changed my life... I can't ask for anymore really and that type of CORO doesn't get you better, it's the medication.*

### *Having a purpose: Psychosocial treatments*

Some participants reflected how engaging in occupation whether this be leisure, educational or vocational was a valuable part of their recovery as these activities gave a sense of: purpose,

achievement, relaxation and soothing, or a sense of progression in life. For Harris, relaxation and achievement was a positive outcome of his activities as was the positive reinforcement from others around this:

> *Harris: It makes me relax I just sit in the dining room, put my music on and draw away. It's so relaxing and see when you put a picture together and it comes out spot on what a feeling that is!... great sense of achievement… Doctors said it, Charge Nurse has said it so it's a good sign when I'm drawing.*

Caelan's activities appeared to give him a sense of achievement and "ownership" over something. Perhaps serving as an antidote to his aforementioned sense of not being a "real person" (see *Found guilty of having a mental illness*):

> *Caelan: I really liked the essays I must admit. I liked the different subjects. I liked that fact that… I'm good with words and I realised that my writings skills was quite good… I swim once every day. I go swimming once a day. Do a bit of gardening. Cutting a hedge today for my brother. I do his gardening once a week... Aye I like ma garden. I do enjoy it.*

Similarly, Magnus and Archie valued learning new skills and gaining a sense of satisfaction in their activities. Having this sense of purpose appeared to serve a role in maintaining hope for the future:

> *Magnus: I did lots of stuff. I did photography, I went down to the Christmas village. I did loadsa stuff yknow activity-wise it was really productive. I made use of my time.*

> *Archie: And I also do cooking groups with one of the OTs [Occupational Therapists]. The OT takes me to the rehab kitchen, which is the kitchen in the rehab unit and we just make something to eat like broccoli and stilton soup, or a pizza or a turkey burger… So it's stuff that I'm able to do under the CORO and I find those things quite satisfying yknow.*

Often participants identified that their activities took place in the context of relationships with staff which was healing in itself, perhaps aiding in preparing them for what life may be like when they achieve CD and reintegrate into the community:

> *Archie: Well on a Thursday I've got a 1:1 social group where one of the OTs takes me to the canteen and we get a hot chocolate and a mocha or something and we just kinda sit and chat for a bit. So that's something that I'm able to do under the CORO and that's something that I quite enjoy, it's something that I look forward to every week.*

Donald reflected on the importance of occupation and the sense of loss of purposeful role and positive social contact experienced when it was no longer available to him and fellow patients:

> *Donald: I worked in the laundry down there. But they shut the laundry down in and moved it to another hospital yknow… Well I think it was stupid, you've got a lot of men. At one time there was a lot of men working there. They need something to do and that was something to do. Me and a few other guys we used to like working there in the laundry.*

Psychological therapy was also recognised as a valuable and acceptable form of intervention by some participants:

> *Magnus: She was a fantastic psychologist. We did some really good work together which helped me so much…*
>
> *Lewis: Like I've put in my advance statement I'm happy to do any kind of psychology work.*

Some reflected on lack of psychological intervention in their treatment plan thus far and indicated a longing to explore this:

> *Caelan: Apart from a psychologist or two yknow I've never actually spoken much. There's never been a lot of therapy, talking therapy – it's all been drugs yknow.*

### *Self-disclosure; navigating new relationships*

Some participants discussed part of the healing process as learning to navigate social interactions their newfound identities, with restrictions to abide by and deciding whether to self-disclose and if so how.

Participants reflected on difficult situations that arose and having information disclosed about them or having to disclose themselves to some extent whether they wanted to do this or not:

> *Lennox: They start asking questions and this and that and it makes you feel uneasy. So one day I said to my friend "Look would you mind telling them [new friends] what the circumstances are?". So they told them and they said "that's fine" and you could tell by the conversation that things were much easier yeah.*
>
> *Harris: People used to ask me out… For coffees and visiting and all that and meet them… I couldn't tell them "Well it's not in my planner". They'd be like "what planner? What you on about?" … tell her I had to shake really…*

For some, learning the most appropriate way to self-disclose was a learning process:

> *Lennox: …You go out with them then you start going on the conversation about being ill and everything and tell them what happened and straight away they put their hands up "oh sorry" but I found out the easiest way. I've been out for a couple of meals and Dr [Name] knows about them all but you don't tell them [about offence and illness] on the first time.*

Some participants discussed the emotional impact this loss of power and privacy had on them:

> *Lewis: I suppose I didn't feel particularly good about it. Yeah I didn't feel good about it at all.*
>
> Magnus: *…it was like "Awwwww shit" it was horrible. Fortunately enough I had already disclosed to her everything that had happened so I wasn't like hiding anything so that made it easier but it was still like "Oh Fucckkk. Just to be intimate or to be in a proper relationship I need to go through this?" It's quite, quite scary and daunting at times.*

For some, there was a sense of the inevitability about disclosure and agreement that disclosure needed to occur. When participants beliefs about disclosure aligned with professionals this appeared to allow participants to accept this:

> *Magnus: This huge bombshell which has to be dropped there's no, there's no trying to get away from it. Trying to, trying to hide from it you know what I mean. Maybe it's a good thing cause there's no skeletons in the closet and it would be but I like to be honest and upfront especially in relationships and show transparency and I guess when you're living under a CORO that's the way it has to be.*

Magnus considered the impact of being under CORO/FMHC for a number of years as a "pause" in his life which meant that rebuilding social connections, old and new, was required:

> *Magnus: Cause it has quite an impact on your life. Cause the way one of my friends says "Look at it you've had ten years out of your life and you've got to try and rebuild that ten years of relationships. Whether it be with family or friends or girlfriends or stuff like that it's all different."*

## Discussion

This study investigated perceptions of the experience of living under CORO in Scotland. IPA revealed that participants naturally attempted to make sense of their journey into FMHC - the links between mental illness and offending – and for some the gravity of CORO took some time to be realised (*How did I end up here?*). The impact of CORO was felt in different ways; some experiencing the systems as punitive and others taking comfort in the safety net CORO

provided (*Impact: Power, punishment, and protection*). Participants reflected on a range of adaptations they developed to the unusual situation they found themselves in; from actively accepting the care and treatment offered, to verbally opposing it but complying with it behaviourally, to finding proscribed and legitimate ways to level the power imbalance, and shifting their focus away from life under CORO, at times engaging in mental avoidance (*Surviving and adapting*). Finally, participants reflected on the different channels of healing (medication, psychosocial treatment, therapeutic relationships, and learning to navigate relationships in healthy ways) and what they found helpful about these (e.g. provided a sense of safety, purpose, self-agency, lessened distress etc) (*Recovery*).

Though IPA research does not aim to provide generalizable findings, instead seeking to shed light on individual narratives of phenomena (Smith et al., 2009) it is argued that those familiar with an area can evaluate the capacity for findings to be generalized to other similar settings (Polit & Beck, 2010; Thorne et al., 2009). Being cognizant of this, the findings and their clinical implications are discussed below.

The findings of previous research – that patients attempt to make sense of what has happened to them, feelings that they lived in the shadow of the past regarding the events that brought them into FMHC, and that they have become a different person by virtue of this experience (Stuart et al., 2017) - were strengthened by those found here (*How did I end up here?*). The findings of the present study also support those of previous international meta-synthesis of ITOs reinforcing that legal processes are commonly poorly understood (Goulet et al., 2019) (*Realising the gravity of CORO*). This study evidenced that some felt that CORO had been inadequately explained and that their understanding of it remained poor for some time after being placed on the order. This may be due to a variety of reasons including deficits in cognitive functioning and attentional processes while acutely unwell. However, the accessibility and understandability of information given to patients regarding their CT may be a factor which is amenable to change. Indeed, the readability of statutory letters supplied by FMH services in NHS Scotland has been shown to be poor; between 11.9-57.6% of issues letters were found to be un-readable (Lim & Bennett, 2020). Further, findings from a Swedish FMH sample demonstrated that 63% of patients reading level was below average for grade 6 (12-13years old), 31% failed to reach grade 4 reading ability (10–11years old) and that around 16% presented with a profile consistent with dyslexia (Svensson et al., 2015). Thus, this population present with significant literacy needs and so information provided regarding their MHCT Act status should be accessible. In addition, restrictions and compulsions should be worded in a way which is clear to both patient and health professionals in order to avoid uncertainty as far as possible.

Participants revealed varied effects of living under CORO from perceptions of punishment, control and coercion to viewing the order as a protective mechanism in their best interests (*Impact: Power, punishment, and protection*). This is in keeping with a meta-synthesis which demonstrated perception of involuntary treatment contrastingly from protection to abuse; a safety net, a form of punishment, and rehospitalisation as the "Sword of Damocles" (Goulet et al., 2019). In addition, the subtheme identified here - *Your life's out of your own hands* - maps on clearly to Stuart and colleagues (2017) theme of *Not having a say in my own life*. *Your life's out of your own hands* speaks to the dilemma patients face in that they are compelled to disclose the inner workings if their psyche yet when they do they run the risk of saying the "wrong thing" which may in their eyes set back their recovery/CD.

Some participants described having been on the order for many years, this being out of their control; are some individuals' remaining on orders for longer than necessary? For example, even when their decision-making capacity has in fact returned (Newton-Howes & Ryan, 2017). Indeed, improved insight does not necessitate discharge from CT for individuals who continue to pose risk of harm or have rapid or severe relapse signature (Dawson & Mullen, 2008). Support to help individuals make their own decisions is lacking (House of Lords Select Committee, 2014; National Institute for Health and Social Care Excellence, 2018; United Nations Committee on the Rights of Persons with Disabilities, 2014) and the current study reinforces the need for this support to be improved to reduce the length of time on CORO where appropriate.

The subtheme - *Found guilty of having a mental illness* - highlighted the perception of some patients that those who present with anti-social attitudes and behaviours but do not experience major mental illness (i.e. those who are sentenced to serve time in prison) are treated more leniently than those who experience mental illness out with their own control and offend when acutely unwell. This appears partly due to the perception of restrictions "without limit of time" to be unjust in comparison to the time limited sentence of those given prison sentences. The difference may lie in those who view CORO's function as caring as opposed to fulfilling a punitive function which fortifies previous research (Tomlin et al., 2018). This subtheme also perhaps reflects the well evidenced public perception of increased dangerousness in those with mental illness (Crisp et al., 2000; Hori et al., 2011; Link et al.,1999; Pescosolido et al., 1999). In addition, this echoes previous findings that the dual role is perceived by patients to impede their recovery (Mezey et al., 2010). This stigma may be even more amplified in those who experience substance use difficulties in addition; a triple stigma (Hartwell, 2004).

The process of epistemic injustice (Fricker, 2007) – unfairness related to knowledge - may be implicated here. One form of this injustice - testimonial injustice – occurs when the integrity of

participants testimonies may be demoted by attributions such as emotional dysregulation and cognitive inaccuracy. In addition, another form of this injustice - hermeneutical injustice – occurs when many aspects of patients' experiences of illness are difficult to comprehend and communicate resulting in gaps in collective knowledge. Further, practitioners, services and systems may be advantaged by training, expertise and inherent favouring of particular styles of communicating and demonstrating testimonies (e.g. formal meetings and letters) in ways that ostracize those with illness (Carel & Kidd, 2014). In simple terms, professionals have the knowledge and experience of the law and mental health system that the patient (at least initially) does not. Individuals presenting with mental distress are particularly exposed to epistemic injustices due to entrenched social stigma (attributions of emotional instability and cognitive unreliability) such that their perspectives and interpretations are commonly overlooked or demoted (Newbigging & Ridley, 2018). For example, some feel their voice is not heard or taken seriously by virtue of having a mental illness:

> *Tom: I would say that ever since I've been in the mental health system my voice hasn't been heard... I tried to get my message across when I first entered the mental health system and it was like nobody was listening at all. They were just deploying rules down upon me for having a mental illness.*

In this study, some of those who perceived CORO as coercive did so as a result of their perception that their voice was not heard or considered reliable because of their status as a person with a severe mental illness. The literature posits that it is unclear whether negative effects of ITOs relates to their coercive elements (Goulet et al., 2009) it would appear this study demonstrates that this may be the case for some. The epistemic injustice which may be at play in this complex context may be lessened by encouraging the voices of those in FHMC in patient advocacy and the recovery movement in which they have previously been unheard (Mezey et al., 2010; Perlin, 2016).

Some participants communicated their discomfort with frequent observation and monitoring in the subthemes *On being a chaperoned adult* and *Always under watch*. Given the high levels of childhood adversity and trauma in his population there is potential for frequent monitoring (e.g. constant observation on wards) to perpetuate paranoia as such it is important to use a trauma informed approach in the monitoring of patients.

The third superordinate theme (*Surviving and Adapting*) derived revealed the ways participants had adapted to the unusual situation they found themselves in. Two forms of compliance were described - *Active acceptance* and *Passive resistance* – which fits with previous findings "*learning to play the game as a strategy"* (Goulet et al., 2019). Some participants appeared to keenly engage with the system and therapeutic options offered. This was perhaps mediated

by these participants largely experiencing CORO as protective; for example, three participants (Archie, Donald, and Magnus) all endorsed subthemes *Protection and safety*, *Active acceptance*, *Reciprocity in relationships*, *Finding the right medication*, *Having a purpose; Psychosocial treatments*. While another subgroup voiced disagreement with the CORO however complied behaviourally. For example, Lewis, Caelan, Bruce and Tom shared subthemes: *Your life's out of your hands*, *Found guilty of having a mental illness,* and *Passive resistance.* As discussed above, this may reflect shared beliefs about the function of CORO/FMHC as punitive and stigmatisation for their dual role. A fourth subgroup advocated coping in the form of shifting attention and avoidance away from the reality of CORO. The literature on this form of avoidant coping - "sealing over" – is well established (McGlashan et al., 1975). Such coping styles are correlated with negative early experiences in childhood, and insecure adult attachment style which is itself associated with less engagement with services (Tait et al., 2004). Given the current knowledge on attachment, it is fitting that those who experience CORO as more punitive/custodial (e.g. those who endorse subthemes *Your life's out of your hands* and *Found guilty of having a mental illness*) also largely tended to endorse the subtheme *Avoidance and shifting focus*.

For the subgroup who endorsed CORO as protective and actively accepted the order this appeared to occur when participants own goals aligned with staffs/services goals for them resulting in engagement and a sense of ownership or agency over it. Again, this reflects previous findings (Canvin et al., 2002; Goulet et al., 2019; Jobling, 2014). Thus, this study reinforces that individuals should be supported to have pro-social agency over their life where possible in line with good lives model principles (Barnao et al., 2016; Ward et al., 2007).

The final superordinate theme concerned the modes of healing participants found beneficial (*Recovery*). This included the use of medication, psychosocial activities, reciprocity in relationships with professionals, and the process of reconnecting in the outside social world and learning to self-disclose in appropriate ways. The relational themes found here fit with previously demonstrated themes such as *trying to fit back in, relationships are more difficult now* (Stuart et al., 2017), *characteristics of a good relationship in a coercive context* (Goulet et al., 2019) and *relationships with staff and patients being important in bringing about recovery* (Mezey at al., 2010). The subthemes found here *Having a purpose: Psychosocial treatments* and *Finding the right medication* echoes those found in previous research regarding medication and psychological work being important in supporting recovery (Mezey et al., 2010). Previous international meta-synthesis highlighted the gaps in knowledge regarding whether positive effects of ITOs are related to the intensity of care and treatment (Goulet et al., 2019). The results of the current study provides preliminary evidence that individuals tend to value and perceive CORO as protective if care and treatment is experienced as helpful,

purposeful, and reciprocal. In addition, it would appear that the availability of psychosocial interventions has improved since the commencement of the MHCT Act in Scotland as most participants discussed ready access to these, though access to psychological input remains limited (SGSR, 2009).

Discussion of mental health staff involvement in personal relationships was noted by most participants who had been CD'd (*On being a chaperoned adult* and *Self-disclosure; Navigating new relationships)*. It is important that this involvement is balanced and based on individual risk management needs in order to allow the protective effect good quality relationships have on reducing offending in this population (Laub et al., 1998; Laub & Sampson, 2001). Indeed, deficits in emotional intimacy with others is shown to be a strong risk factor for sexual offending (Mann et al., 2010). The subtheme *Self-disclosure; Navigating new relationships* speaks to a psychological and social need for some patients to be supported appropriately in learning skills establishing and maintaining healthy relationships in addition to disclosing sensitive personal information in a measured manner. Thus, appropriate psychosocial intervention in this is promoted by the findings here.

Other jurisdictions utilise similar procedures which operate without limit of time – such as the Section 37/41 orders in England, preventive detention in Germany (Steinböck, 2009; Basdekis-Jozsa et al., 2013), indefinite involuntary treatment in New Zealand (Saya et al., 2019) – it is possible that the issues and implications discussed above may be similarly relevant to these contexts.

## Limitations

Six individuals were offered the opportunity to take part in this study and declined; they may have provided a different perspective which was unable to be represented in this study. As the sample contained those on CD in the community and those living as inpatients the sample was not fully homogenous however this has allowed for between group comparison that would otherwise not have been possible.

Interestingly, the discharge status of participants did not tend to be associated with their coping styles which perhaps suggests that different adaptations result in the same outcome (of CD), though potentially at varying paces. This study sampled from 2 Scottish health boards thus increasing generalisability of the findings across these sub-populations.

### Future research

Future research should explore patients understanding or lack thereof of their legal status, the implications of this and how best to increase understanding when their mental state allows. Investigation of the experiences of those under COs and CTOs in Scotland may delineate any differences in the impact and needs of these populations compared to those under CORO. In addition, examination of the experiences of those in FMHC where admissions tend to be significantly longer and whether the development of longer relationships with staff and fellow patients and whether this serves a protective function compared to those cared for in general adult mental health. Finally, exploring whether interventions to support decision making capacity reduce length of time under CORO.

## Conclusion

The effectiveness of CT is widely debated and gaps remain in the literature regarding whether ITOs promote recovery and whether the positive effects of ITOs are related to the intensity of care and treatment and negative effects to its coercive elements (Goulet et al., 2019). People living under CORO face CT and restriction “without limit of time”. The four superordinate themes derived in the current study were echoed by previous findings (Goulet et al., 2019; Mezey et al., 2010; Stuart et al., 2017). Though they described the challenges encountered by people living under CORO (e.g. difficulties understanding legal processes, the stigma of having dual roles) they also highlighted the adaptive ways individuals adjust in order to progress through a complex system, and the methods which aid them in recovery (e.g. medication, psychosocial interventions, reciprocity in relationships with staff and learning how best to self-disclose).

Though not without its weaknesses, this study provides valuable insight into a novel area in a population whose experiences are often unheard (Mezey et al., 2010). Areas for future research and clinical implications are discussed in light of the findings of the study.

The authors hope that the current study has presented an account from which services and individuals can consider the complex position those under CORO find themselves, and the ways they can be supported to progress in their recovery.

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# Appendices

## Appendix 1. Journal Author Guidelines: Behavioral Sciences & the Law

### Author Guidelines

**Initial manuscript submission.** Each issue of *Behavioral Sciences & the Law* primarily is themed, and there is a rotating editorship. The preferred submission method is by e-mail attachment (Word Format) to: email: **cewing@buffalo.edu**. Each issue will include a number of articles on the specific theme of the issue. As space permits, there will be a section of pieces dealing with other behavioral-science-and-law topics. Acceptable contributions include research reports, special perspectives, book reviews, adversary forums, and a "practitioner's corner" feature. One issue each year will be devoted to non-themed contributions.

**Pre-submission English-language editing.** Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found at **http://wileyeditingservices.com/en/**. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

Submission of a manuscript will be held to imply that it contains original unpublished work and is not being submitted for publication elsewhere at the same time. Submitted material will not be returned to the author.

**Electronic submission.** The electronic copy of the final, revised manuscript **must** be sent to the Editor **together with** the paper copy. Disks should be PC or Mac formatted; write on the disk the software package used, the name of the author and the name of the journal. We are able to use most word processing packages, but prefer Word, WordPerfect and TeX or one of its derivatives.

Illustrations must be submitted in electronic format where possible. Save each figure as a separate file, in **TIFF** or **EPS** format preferably, and include the source file. Write on the disk the software package used to create them; we prefer dedicated illustration packages over tools such as Excel or Powerpoint.

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Please find the Wiley preprint policy **here.**

This journal accepts articles previously published on preprint servers.

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Behavioral Sciences and the Law will consider for review articles previously available as preprints. Authors may also post the submitted version of a manuscript to a preprint server at any time. Authors are requested to update any pre-publication versions with a link to the final published article.

**Data Protection**

By submitting a manuscript to or reviewing for this publication, your name, email address, and affiliation, and other contact details the publication might require, will be used for the regular operations of the publication, including, when necessary, sharing with the publisher (Wiley) and partners for production and publication. The publication and the publisher recognize the importance of protecting the personal information collected from users in the operation of these services, and have practices in place to ensure that steps are taken to maintain the security, integrity, and privacy of the personal data collected and processed. You can learn more at **https://authorservices.wiley.com/statements/data-protection-policy.html**

**Manuscript style.** The language of the journal is English. All submissions, including book reviews, must have a title, be printed on one side of the paper, be double-line spaced and have a margin of 3 cm all round. Illustrations and tables must be printed on separate sheets, and not be incorporated into the text.

- The **title page** must list the full title and names and affiliations of all authors. Give the full address, including email, telephone and fax, of the author who is to check the proofs.
- Include the name(s) of any **sponsor(s)** of the research contained in the paper, along with **grant number(s)**.

- Supply an **abstract** of around 150 words for all articles (except book reviews). An abstract is a concise summary of the whole paper, not just the conclusions, and is understandable without reference to the rest of the paper. It should contain no citation to other published work.

**Reference style.** References should be prepared according to the *Publication Manual of the American Psychological Association* (6th edition). This means in text citations should follow the author-date method whereby the author's last name and the year of publication for the source should appear in the text, for example, (Jones, 1998). The complete reference list should appear alphabetically by name at the end of the paper.

A sample of the most common entries in reference lists appears below. Please note that a DOI should be provided for all references where available. For more information about APA referencing style, please refer to the **APA FAQ**. Please note that for journal articles, issue numbers are not included unless each issue in the volume begins with page one.

**Journal article**

Example of reference with 2 to 7 authors

Beers, S. R. , & De Bellis, M. D. (2002). Neuropsychological function in children with maltreatment-related posttraumatic stress disorder. *The American Journal of Psychiatry, 159,* 483– 486. doi:**10.1176/appi.ajp.159.3.483**.

Ramus, F., Rosen, S., Dakin, S. C., Day, B. L., Castellote, J. M., White, S., & Frith, U. (2003). Theories of developmental dyslexia: Insights from a multiple case study of dyslexic adults. *Brain, 126*(4), 841–865. doi:**10.1093/brain/awg076**.

Example of reference with more than 7 authors

Rutter, M., Caspi, A., Fergusson, D., Horwood, L. J., Goodman, R., Maughan, B., … Carroll, J. (2004). Sex differences in developmental reading disability: New findings from 4 epidemiological studies. *Journal of the American Medical Association, 291*(16), 2007–2012. doi: **10.1001/jama.291.16.2007**

**Book edition**

Bradley-Johnson, S. (1994). *Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school* (2nd ed.). Austin, TX: Pro-ed.

**Illustrations.** Supply each illustration on a separate sheet, with the lead author's name and the figure number, with the top of the figure indicated, on the reverse. Supply original **photographs**; photocopies or previously printed material will not be used. Line artwork must be high-quality laser output (not photocopies). Tints (grey shading) is not acceptable. Lettering must be of a reasonable size that would still be clearly legible upon reduction, and consistent within each figure and set of figures. Supply artwork at the intended size for printing, sized to the text width of 208mm × 126mm maximum.

## Appendix 2: Prisma Checklist

| Section/topic | # | Checklist item | Reported on page # |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | |

| | | | |
|---|---|---|---|
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$) for each meta-analysis. | |

| | | | |
|---|---|---|---|
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | |
| **RESULTS** | | | |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | |
| **DISCUSSION** | | | |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | |

| | | | |
|---|---|---|---|
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | |
| **FUNDING** | | | |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | |

*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

## Appendix 3: Reason for exclusion of each full-text article

| Reference | Reason for Exclusion |
|---|---|
| **Jeandarme, I., Habets, P., Oei, T. I., & Bogaerts, S. (2016). Reconviction and revocation rates in Flanders after medium security treatment. *International Journal of Law and Psychiatry*, *47*, 45-52.** | Did not examine factors associated with revocation, return to hospital or maintenance of CR. |
| **Roskes, E., & Feldman, R. (1999). A collaborative community-based treatment program for offenders with mental illness. *Psychiatric Services*, *50*(12), 1614-1619.** | Descriptive statistics only. |
| **Roskes, E., Feldman, R., Arrington, S., & Leisher, M. (1999). A model program for the treatment of mentally ill offenders in the community. *Community Mental Health Journal*, *35*(5), 461-472.** | Review paper. |
| **McGreevy, M. A., Steadman, H. J., Dvoskin, J. A., & Dollard, N. (1991). New York State's system of managing insanity acquittees in the community. *Psychiatric Services*, *42*(5), 512-517.** | Did not examine factors associated with revocation, return to hospital or maintenance of CR. |
| **Lamb, H. R., Weinberger, L. E., & Gross, B. H. (1988). Court-mandated community outpatient treatment for persons found not guilty by reason of insanity: A five-year follow-up. *The American Journal of Psychiatry, 145*(4), 450–456.** | Descriptive statistics only. |
| **Rintelen, E., & Gabbert, T. (1986). Rehabilitation of psychiatric patients and mentally handicapped offenders--a long-term study (1969-1984). *Die Rehabilitation*, *25*(1), 24-29.** | Written in German. |
| **Norko, M. A., Wasser, T., Magro, H., Leavitt-Smith, E., Morton, F. J., & Hollis, T. (2016). Assessing insanity acquittee recidivism in Connecticut. *Behavioral Sciences & the Law*, *34*(2-3), 423-443.** | Did not examine factors associated with revocation, return to hospital or maintenance of CR |
| **Novosad, D., Banfe, S., Britton, J., & Bloom, J. D. (2016). Conditional Release Placements of Insanity Acquittees in Oregon: 2012–2014. *Behavioral Sciences & the Law*, *34*(2-3), 366-377.** | Did not examine factors associated with revocation, return to hospital or maintenance of CR. |
| **Segal, S. P., Preston, N., Kisely, S., & Xiao, J. (2009). Conditional release in Western Australia: effect on hospital length of stay. *Psychiatric Services*, *60*(1), 94-99.** | Study population sampled from general adult psychiatric patients. |
| **Wright II, E. E. (2006). *The utility of the Substance Abuse Subtle Screening Inventory-3 (SASSI-3) in early detection of substance abuse disorders in not guilty by reason of insanity acquitees*. The University of Toledo.** | Unpublished study. |
| **Wiederanders, M. R., Bromley, D. L., & Choate, P. A. (1997). Forensic conditional release programs and outcomes in three states. *International Journal of Law and Psychiatry, 20*(2), 249–257.** | Descriptive statistics only. |
| **Williams, M. H., Bloom, J. D., Faulkner, L. R., Rogers, J. L., & Godard, S. L. (1988). Drug treatment refusal and length of hospitalization of insanity acquittees. *Journal*** | Did not examine factors associated with revocation, return to hospital or maintenance of CR. |

***of the American Academy of Psychiatry and the Law Online*, *16*(3), 279-284.**

## Appendix 4: Adapted version of the Appraisal tool for Cross-Sectional Studies (AXIS) tool

(Downes, Brennan, Williams, & Dean, 2016)

Appraisal tool for Cross-Sectional Studies (AXIS) (Adapted for use in current study)

**Study (First Author, Year):**

*Items/questions added to original AXIS tool.

| | | Yes | No | Do not know/comment *Well-covered/adequately covered/ inadequate" |
|---|---|---|---|---|
| *Introduction* | | | | |
| 1 | Were the aims/objectives of the study clear? | | | |
| *Methods* | | | | |
| 2 | Was the study design appropriate for the stated aim(s)? | | | |
| 3 | Was the sample size justified? | | | |
| 4 | Was the target/reference population clearly defined? (Is it clear who the research was about?) | | | |
| 5 | Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation? | | | |
| 6 | Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation? | | | |
| 7 | Were measures undertaken to address and categorise non-responders? | | | |
| 8 | Were the risk factor and outcome variables measured appropriate to the aims of the study? | | | |
| 9 | Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously? | | | |
| 10* | *Was follow up period an appropriate length to allow for possible revocation to occur? I.e. 2 years or more | | | |
| 11 | Is it clear what was used to determined statistical significance and/or precision estimates? (e.g. p-values, Confidence Intervals). *Effect sizes must be reported for "Well-covered" rating | | | |

| | | Yes | No | Do not know/comment *Well-covered/adequately covered/ inadequate” |
|---|---|---|---|---|
| 12 | Were the methods (including statistical methods) sufficiently described to enable them to be repeated? | | | |
| 13* | *Were confounding factors identified? Were strategies to deal with confounding factors stated? | | | |
| *Results* | | | | |
| 14 | Were the basic data adequately described? | | | |
| 15 | Does the response rate raise concerns about non-response bias? *Rate as “inadequate” if authors do not mention missing data | | | |
| 16 | If appropriate, was information about non-responders described? | | | |
| 17 | Were the results internally consistent? | | | |
| 18 | Were the results presented for all the analyses described in the methods? | | | |
| *Discussion* | | | | |
| 19 | Were the authors’ discussions and conclusions justified by the results? | | | |
| 20 | Were the limitations of the study discussed? | | | |
| *Other* | | | | |
| 21 | Were there any funding sources or conflicts of interest that may affect the authors’ interpretation of the results? | | | |
| 22 | Was ethical approval or consent of participants attained? | | | |

## Appendix 5: Variables & strength of relationship to outcome variables

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| Bertman-Pate (2004)* | Kruksall-Wallis tests | Revocation status | <u>Non-revoked</u> group had significantly:<br>longer length of stay in outpatients program, [η2 = 0.12, *d* = 0.73, 0.116, *p* = 0.000]<br>fewer previous psychiatric hospitalizations [η2 = 0.03, *d* = 0.34, *p* = 0.037]<br>more frequent diagnosis of mental retardation [η2 = 0.04, *d* = 0.42, *p* = 0.014]<br>less frequent diagnosis of schizophrenia [η2 = 0.03, *d* = 0.35, *p* = 0.03]<br>fewer previous arrests [η2 = 0.04, *d* = 0.39, *p* = 0.021]<br>higher incidence of 0 incidents [η2 = 0.18, *d* = 0.93, *p* = 0.000]<br>fewer incidents [η2 = 0.03, *d* = 0.32, *p* = 0.049] |
| Bloom (1986)* | ANOVA | Revoked vs. remained in treatment program | Patients who remained in treatment program (average of 23months) compared to only 9 months for those who were revoked, highly significant time difference (*d* = 1.16, F= 18.89, p< .0001).<br>No difference in demographic variables between those participants revoked by the treatment team/programme and those remaining in program. |
| Callahan (1998) | Unstated univariate analysis.<br>Logistic Regression | Revocation status | <u>Revocation</u><br>*Bivariate analyses*<br>Substance abuse history was significantly related to revocation [OR = 2.73, p <. 001]<br>*Stepwise logistic regression*<br>A stepwise logistic regression equation including several variables showed that only:<br>Employment [OR = 0.51, p < . 05] and<br>Substance abuse history [OR= 2.13, p < .05] had significant independent effects on the probability of revocation, controlling for the effect of between state differences.<br><u>Non-revocation</u><br>*Bivariate analyses*<br>Persons for whom the target offense was their first offense were less likely to have their CR revoked than those for whom it was not [OR = 0.55, p < .01] |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| | | | White individuals were less likely than non-whites to have their CR revoked [OR = 0.66, p < .05] |
| | | | Married persons were less likely than unmarried persons to have their CR revoked [OR = 0.34, p < .001] |
| | | | Employed persons were less likely than unemployed persons to have their CR revoked [OR = 0.51, p < .05] |
| | | | Persons living with family were more likely to have their CR revoked than those living alone [OR = 1.58, p < .05] |
| Hayes (2014)* | Survival analysis using Kaplan-Meier estimator. Chi-square tests. Fisher's Exact test. | Revocation status | <u>Variables found to be associated with revocation of 1st CR</u> |
| | | | *Fisher's Exact test* |
| | | | Aboriginal and Torres Strait Islander status ($p$ < 0.002) [Unable to calculate effect size due to lack of information in paper and supplemental note] |
| | | | *Chi square analyses* |
| | | | Age at first offence (<25 years) ($\eta^2$ = 0.03, d = 0.33, $p$ < 0.03) |
| | | | Antisocial personality traits ($\eta^2$ = 0.12, d = 0.75,$p$ < 0.00) |
| | | | Substance abuse ($\eta^2$ = 0.11, d = 0.71, $p$ < 0.00) |
| | | | Poly-substance abuse ($\eta^2$ = 0.11, d = 0.70, $p$ < 0.00) |
| | | | Previous prison ($\eta^2$ = 0.17, d = 0.91, $p$ < 0.00) |
| | | | Previous conviction ($\eta^2$ = 0.10, d = 0.65, $p$ < 0.00) |
| | | | Age at CR (<35) ($\eta^2$ = 0.21, d = 0.29, $p$ < 0.05) |
| | | | Breach prior to CR ($\eta^2$ = 0.08, d = 0.60, $p$ < 0.00) |
| | | | Unemployed at CR ($\eta^2$ = 0.07, d = 0.56, $p$ < 0.00) |
| | | | <u>Variables found to predict revocation after CR</u> |
| | | | *Binary Logistic Regression* |
| | | | Age at conditional release (< 35 years) ($p$ <.04) |
| | | | Unemployed at conditional release ($p$ <.01) |
| | | | <u>Variables found to be associated with one or more hospital readmission after CR</u> |
| | | | *Chi square analyses* |
| | | | Residual symptoms at CR ($\eta^2$ = 0.07, d = 0.56, $p$ < .00) |
| | | | Substance abuse disorder ($\eta^2$ = 0.05, d = 0.46, $p$ < .02) |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| | | | Unemployed at CR ($\eta^2 = 0.02$, d = 0.31, $p < .03$) (found to inversely predict) |
| | | | <u>Variables found to predict hospital readmission after CR</u> |
| | | | *Binary Logistic Regression* |
| | | | Residual symptoms at CR ($p < .01$) |
| | | | Substance abuse disorder ($p < .02$) |
| Jewell (2018) | Cox regression survival techniques | Time to recall (readmission to secure care) & risk of recall | <u>Shorter time to recall (readmission to secure care)</u> |
| | | | *Cox regression – univariate predictors of recall* |
| | | | Younger age (≤ 38) (HR 1.89; 95% CI 1.02–3.49; p = 0.04), |
| | | | non-white ethnicity (HR 3.44; 95% CI 1.45–8.13, p = 0.005), |
| | | | substance abuse history (HR 2.52; 95% CI 1.17–5.43, p = 0.02), |
| | | | specifically, cannabis (HR 2.18, 95% CI 1.14-4.19; p = 0.02) and/ or stimulant abuse (HR 2.06; 95% CI 1.15-3.71; p = 0.02) |
| | | | early violence (HR 1.90; 95% CI 1.03–3.50), |
| | | | early childhood maladjustment (HR 1.92; 95% CI 1.01–3.68), |
| | | | treatment with a depot medication (HR 2.17; 95% CI 1.14–4.11; p = 0.02), |
| | | | being known to mental health services (HR 3.44; 95% CI 1.06–11.16; p = 0.04), |
| | | | psychiatric admission prior to the index admission (HR 2.44; 95% CI 1.08–5.52; p = 0.03) |
| | | | HCR-20 H2 young age at first violent incident (HR 1.90; 95% CI 1.03-3.50; p = 004) |
| | | | HCR-20 H8 early maladjustment (HR 1.92; 95% CI 1.01-3.68; p = 0.05) |
| | | | *Post-hoc Kaplan-Meier survival analysis of above variables* |
| | | | After adjusting for personality disorder, prior supervision failure, index offence, and past forensic history, results were largely unchanged except for the effect of H8 early childhood maladjustment was reduced to approaching significance (HR 2.11; 95% CI 0.90-4.94; p = 0.09). |
| | | | <u>Longer time to recall</u> |
| | | | *Cox regression* |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points)<br><br>Treatment with clozapine reduced the risk of recall to hospital (HR 0.40; 95% CI 0.20–0.79 p = 0.009).<br><br>*Post-hoc Kaplan-Meier survival analysis of significant independents predictors of time to recall*<br><br>Forensic patients treated with clozapine of white ethnicity who did not experience early childhood maladjustment survived longer following CD.<br><br>The mean time to recall for patients:<br><br>On clozapine was 4.44years (95% CI = 3.74-5.14) compared to 3.08 years (95% CI = 2.41-3.74) for those not on clozapine.<br><br>Patients of white ethnicity survived on average of 4.65 years (95% CI = 3.46-5.00) vs 3.09 years (95% CI 3.46-5.00) for patients of non-white ethnicity<br><br>Individuals who did not experience early childhood maladjustment survived an average of 4.23 years (95% CI = 3.46-5.00) compared to 3.30 years (95% CI = 2.62-3.98) for patients who had experienced this.<br><br><u>Risk of recall (readmission to secure care)</u><br><br>*Cox Regression – multivariate predictors of time to recall*<br><br>Two-fold increase in recall risk for:<br><br>Non-white ethnicity (HR 3.06; 95% CI 1.20-7.79; p = 0.02)<br><br>HCR-20 H8 Early childhood maladjustment (H 2.22; 95% 1.05-4.73; p = 0.04)<br><br>Not being treated with clozapine (HR 2.66; 95% CI 1.22-5.78; p = 0.01) |
| Manguno-Mire (2014) | Kruksall-Wallis. Logistic regression. | Revocation status | <u>Revoked group</u><br><br>*Bivariate analyses*<br><br>Higher number of “incidents” while on CR (3.9 in revoked group vs 1.4 incidents in non-revoked group) ($\eta^2 = 0.307$, d = 1.331, $p < 0.01$)<br><br>A younger age at first offense [$\eta^2 = 0.029$, d = 0.344, p = 0.01]<br><br>Higher number of previous arrests [$\eta^2 = 0.028$, d = 341, p = 0.01] were significantly related to revocation.<br><br>Personality disorder [$\eta^2 = 087$, d = 0.6174, $p < 0.01$]<br><br>Having at least one incident while on CR [$\eta^2 = 0.2082$, d = 1.0255, $p < 0.01$] |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points)<br><br>Lower number of days to first incident for those who were revoked (Mdn 37.5 vs 568 days) [Kaplan-meier estimates used, $p < 0.01$]<br><br><u>Non-revoked group</u><br><br>Having medicare [$\eta^2 = 0.0365$, d = 0.3894, p = 0.01]<br><br>Having social security disability income [$\eta^2 = 0.0446$, d = 0.4322, p = 0.01]<br><br>*Logistic regression*<br><br>Success on conditional release was predicted by social security disability income [p = 0.0034; OR = 0.3, 95% CI: 0.14-0.68], not having a personality disorder [p = 0.0020; OR = 7.2, 95% CI: 2.1-25.1], and having fewer total incidents in the program [p< 0.0001; OR = 1.6, 95% CI: 1.3-2.0]. |
| Marshall (2014) | Chi-square, ANOVA, Logistic regression | Forensic Rehospitalisation | <u>Readmitted involuntarily to a forensic hospital if:</u><br><br>They resided with family [$\eta^2 = 0.0209$, d = 0.2924 $\chi 2 = 7.45$, p = 0.006]<br><br>Had an arrest compared to no arrests [$\eta^2 = 0.1411$, d = 0.8106, $\chi 2 = 50.23$, <0.001].<br><br>Report higher rates of substance use [*d*= 0.33]<br><br><u>Not readmitted involuntarily to a forensic hospital if:</u><br><br>Fewer community psychiatric admissions (M = 0.27, SD = 0.82) than both voluntarily readmitted IAs (M= 0.59, SD = 0.81) with a small effect size (Cohen's d= 0.39) and involuntarily admitted IAs (M= 0.63, SD = 0.99) with a large effect size (Cohen's d= 0.99)<br><br>Longer period of time in the community prior to their first psychiatric admission with very large effect size (*d*= 2.96) if voluntarily readmitted, and those involuntary readmitted also with a very large effect size (*d*=2.37).<br><br>*Logistic regression*<br><br><u>Predicting Forensic readmission</u><br><br>Had arrests compared to no arrests (OR=2.87, p=0.009)<br><br>Non-compliance with treatment (i.e. housing & family placement) (OR=1.10, p = 0.04)<br><br><u>Predicts success/maintaining CR</u> |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| | | | Longer duration in community prior to first psychiatric admission (OR=0.83, p < 0.001) |
| Monson (2001)* | Hierarchical logistic and cox regressions by step. Chi square. | Revocation status | <u>Revoked group</u> |
| | | | Minority participants [$\eta^2 = 0.06$, d = 0.50, p=.01] |
| | | | Prior criminal history [$\eta^2 = 0.04$, d = 0.41, p=.02] were less likely to maintain their CR. |
| | | | *Hierarchical Logistic Regression* |
| | | | Minority status was only significant predictor in the model with approximately 25% less chance for successful maintenance of a CR [$\chi^2(22)=36.59$,p =.03]. |
| | | | *Cox Regression* |
| | | | Minority status and substance abuse diagnosis were each associated with around 2.25 times greater likelihood of revocation and prior criminal history was associated with the likelihood of revocation at over 2 times greater [$\chi^2$ (22)=36.59, p=.03]. |
| | | | <u>Non-revoked group</u> |
| | | | *Bivariate analyses* |
| | | | Participants discharged to live with their family of origin or alone/semi-independent living [$\eta^2 = 0.07$, d = 0.54, p=.05] were more likely to maintain their conditional release. |
| Parker (2004) | Univariate & multivariate logistic regression. | Revocation status (successful) & Rehospitalisation and/or arrest while on CR | <u>Group who had been hospitalised and/or arrested while on CR</u> |
| | | | *Univariate logistic regression* |
| | | | Length of potential CR emerged as a statistically significant predictor of hospitalization or arrest [OR= 1.37; 95% CI: 1.03–1.84; p= .03]. |
| | | | *Multivariate logistic regression* |
| | | | When 3 factors (paranoid schizophrenia, offense of murder, and length of potential CR were utilized in multivariate logistic regression analyses, both potential CR [OR = 1.5; 95% CI 1.1–2.1; p=.01] and a diagnosis of paranoid schizophrenia [OR = 0.4; 95% CI: 0.1–1.0; p = .05] were significant predictors of the outcome of hospitalization or arrest, though in opposite directions (paranoid schizophrenia as protective factor for hospitalisation and/or arrest), and an NGRI offense of murder ($p$ = .06) trended towards being a significant predictor. The overall model fit of these three factors was highly significant. |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| | | | <u>Group who successfully maintained CR</u> |
| | | | *Univariate logistic regression* |
| | | | A diagnosis of paranoid schizophrenia showed a trend (*p* = .06) toward being a protective factor for hospitalization or arrest, as did an NGRI offense of murder (*p* = .08). |
| Riordan (2006) | Logistic regression | Recall & Readmission | <u>Recall</u> |
| | | | Patients were five times more likely to be recalled to hospital if they did not have a live-in significant others than if they did have the support of a live-in other [OR = 4.84; 95% CI: 1.69-13.86, p values not reported]; 71.2% of patients were correctly identified as being recalled to hospital by these variables. |
| | | | <u>Readmission</u> |
| | | | Patients were six times more likely to be readmitted to hospital if they misused drugs [OR = 6.12; 95% CI: 1.24-30.12; no *p* values reported] and nine times more likely if they self-harmed [OR = 9.08; 95% CI: 1.07-77.05; no *p* values reported]. |
| Salem (2015) | Cox Regression | Readmission | <u>Increasing risk of readmission</u> |
| | | | *Cox regression* |
| Québec, Canada. | | | Independent housing put individuals at 1.36 times risk of readmission compared with supportive housing (p .034, 95% CI [1.02, 1.81]). |
| | | | Number of psychiatric hospitalizations before index verdict (exp(b) 2.23, p .001, 95% CI [1.71, 2.91]). |
| | | | <u>Lowering risk of readmission</u> |
| | | | Older age at index verdict (exp(b) .84, p .002, 95% CI [0.75, 0.93]), |
| | | | Being female (exp(b) .57, p .007, 95% CI [0.38, 0.86]) |
| Stoner (2002) | Chi-square, Fisher's exact test analyses, Student's t-test | Revocation status & length of maintenance of CR | Clozapine-treated patients 0/8) were significantly less likely to be revoked than those treated with haloperidol (10/17) (p=0.046) |
| | | | Clozapine-treated patients had significantly longer average months on release compared to those treated with haloperidol (53.5 months on release vs 29.5 months) (p = 0.004) |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points)<br><br>[Not possible to calculate ES due to lack of information in paper] |
| Tellefsen (1992) | Canonical correlation, Two stepwise Discriminant analysis. | Predicting Revocation<br><br>Predicting Rehospitalization | <u>Predicting revocation</u><br><br>*Two stepwise Discriminant analysis*<br><br>Patients discharged from state facility:<br><br>Race (1.7*), prior functioning (-1.6*), adjustment at state hospital (-1.2*), birth order (.8*) (in rank order).<br><br>The above variables correctly classified 76.9 percent of the patients who were revoked and 6 patients (26.1 %) as false positives.<br><br>Patients discharged from regional facilities:<br><br>Prior functioning (-6.1*), hospital assessment at state hospital (5.8*), marital status (5.1*), severity of instant offense (-3.6), Race (2.8), adjustment at state hospital (2.4), hospital assessment at regional hospital (1.7), GAF at state hospital discharge (1.4), GAF at regional discharge (1.4), Adjustment at regional (-.9). The above variables classified 95.8% of the patients correctly. Discriminant analysis revealed extremely high predictive ability for regionalised patients; 10 variables correctly predicted 100% of the regionalised patients who were revoked and predicted one false positive.<br><br><u>Predicting Rehospitalization - not hospitalized if:</u><br><br>Patients discharged from state facility:<br><br>Occupation (1) 2.8<br><br>NS Prior functioning (2) 2.3<br><br>Age (3) .8<br><br>The above variables correctly classified 83% of those 23 patients who were rehospitalized during CR and 54% of those not rehospitalized.<br><br>Patients discharged from regional facilities:<br><br>Successful Hospital adjustment (1) 2.3<br><br>Age between 25-35 (2) 1.6<br><br>GAF over 50 at regional discharge (3) -1.6<br><br>Considerably improved at Hospital assessment at regional (4) -.9 |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points)<br><br>The above variables correctly predicted 80% of the patients not rehospitalized and 92 percent of those rehospitalized.<br><br>[unstandardized canonical correlations] |
| Vitacco (2008) | Fisher's exact tests<br><br>Logistic regression | Revocation status | <u>Revocation</u><br><br>*Fisher's exact tests*<br><br>Antisocial personality disorder diagnosis ($X^2$ = 3.30, $p$ = .05).<br><br>Substance abuse diagnosis ($X^2$ = 11.26, $p$ = .001).<br><br>Requiring short-term hospitalizations in a non-forensic facility (for short term stabilization and medication adjustments) while on CR ($X^2$ = 19.07, $p$ =.001).<br><br>Being place under high risk or intensive supervision ($X^2$ = 19.02, $p$ = .001) when compared to those under medium or minimum supervision.<br><br>*Hierarchical logistic multiple regression*<br><br>In a model, below factors were significantly related to failure:<br><br>Substance-abuse diagnosis (CI 95%: 1.15-3.00; p = .04),<br><br>Higher supervision level (p < .001),<br><br>Mental health issues requiring short-term hospitalizations in a non-forensic facility ($p$ = .001).<br><br>Overall, the model accounted for a modest amount of variance ($R^2$ = 14.5) associated with failure of conditional release. |
| Vitacco (2011) | Logistic regression | Revocation status | <u>Revocation</u><br><br>Requiring short-term hospitalization ($p$ = .002) [Unstated statistical method]<br><br>*Logistic regression*<br><br>A model including age, mood disorder, number of charges, short term hospitalization, and supervision level was a significant predictor of the outcome variable CR and accounted for 15.8% of the variance [Wald = 9.82, $X^2$ (5) = 13.08, p = .02].<br><br>Short-term hospitalization was the only significant predictor of revocation of CR. |
| Vitacco (2014) | Logistic regression/ multivariate | Revocation status & time to recall | <u>Predicted revocation on CR</u><br><br>*Logistic regression* |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| | survival analysis. | | model predicting conditional release outcome was significant [$X^2(5) = 25.47$, $p < .001$], but the overall variance accounted for was modest, Cox and Snell $R^2$ 18.3%. Notably, four factors were significant predictors of conditional release revocation:<br><br>previous failure on conditional release [Exp(β) = 0.26; CI 95%: 0.10-0.64; p = .004]<br><br>nonadherence with hospital treatment [Exp(β) = 0.22; CI95%: 0.54–0.92; p = .04]<br><br>number of previous violent charges [Exp(β) = 1.16; CI 95%: 1.01-1.33; p = .03] and<br><br>dangerousness to others [Exp(β) = 3.53; CI 95%: 0.88-14.20, p = 0.08].<br><br>This regression model resulted in a relatively high correct classification percentage related to conditional release outcome (i.e., 81.0%).<br><br><u>Time to revocation</u><br><br>M*ultivariate survival analysis using a Cox regression*<br><br>The multivariate survival analysis using a Cox regression was significant, [$X^2(4) = 23.46$, $p < .001$. Three variables were predictive of shorter time on conditional release:<br><br>previous failure on conditional release ($p < .001$),<br><br>number of previous violent charges ($p = .02$), and<br><br>number of previous charges ($p = .03$).<br><br>Notably, nonadherence with hospital treatment, which was related to conditional release revocation, did not predict time to revocation ($p = .26$) |
| Vitacco (2018) | ANOVA, Logistic regression, Cox regression. | Revocation status & Imminence to revocation | <u>Revocation</u><br><br>*ANOVA*<br><br>Exposure to destabilisers [$p < .05$; $d = -.28$; CI 95%: -.41--.11]<br><br>Stress [$p < .05$; $d = -.31$; CI 95%: -.41 - .14]<br><br>(Items from the HCR-20, both from the Risk Management (RM) scale differed as a function of CR revocation. Both items generated a small adverse effect.)<br><br>*Logistic Regression*<br><br>A logistic regression was used to test CR outcome with the 3 scales from the HCR-20. This produced nonsignificant results [$X^2$ (3) = 2.37, p = .50] and accounted for only 1% of variance (Cox and Snell $R^2$) related to CR outcome. |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| | | | <u>Imminence to revocation</u><br>M*ultivariate survival analysis using a Cox regression using individual risk variables*<br>Three variables were predictive of shorter time on CR:<br>Number of offenses (p = .006),<br>Exposure to destabilizers (p =.001),<br>Substance abuse diagnosis (p = .003)<br>[no ES reported for this] |
| | | | M*ultivariate survival analysis using a Cox regression on HCR-20 scales*<br>This model did not predict imminence to revocation, p = .20. The H scale (p = .96) and the C scale (p = .76) were very limited in predicting imminence to CR, but the RM scale was right at the minimum (p = .051) for predicting revocation imminence.<br>[no ES reported for this] |
| Wiederanders (1994)* | ANOVA | Revoked or restored outcome | Employment, revoked group had significantly lower scores than the restored group (F = 30.76, p <.0001, *d* = 0.69)<br>Social supports, revoked group has significantly lower scores than the restored group (F = 20.02, p <.0001, *d* = 0.61)<br>Substance abuse (recent & present use), revoked group had significantly lower scores than the restored group (F = 9.11, p <.01, *d* = 1.07).<br>Independence and compliance, revoked group had significantly lower scores than the restored group (F = 54.36, p <.0001, *d* = 1.23)<br>Unobtrusiveness, revoked group had significantly lower scores than the restored group (F = 12.75, p <.0001, *d* = 0.43)<br>Self-confidence, revoked group had significantly lower scores than the restored group (F = 18.3, p <.0001, d = 0.81)<br>Responsibility, revoked group had significantly lower scores than the restored group (F = 21.95, p <.0001, d = 0.69)<br>Paranoid, revoked group had significantly lower scores than the restored group (F = 13.74, p <.0001, d = 0.33)<br>Psychotic, revoked group had significantly lower scores than the restored group (F = 14.42, p <.0001, d = 0.12) |

| First Author (Year) | Statistical analysis | Outcome variable assessed | Variables and strength of relationship to outcome variable |
|---|---|---|---|
| | | | (* denotes studies where ES were calculated by main author, round to 2 decimal points) |
| | | | Anxiety & depression, revoked group had significantly lower scores than the restored group (F = 10.63, p <.001, *d* = 0.70) |
| | | | Risk & dangerousness, revoked group had significantly lower scores than the restored group (F = 43.75, p <.0001, d = 0.99) |
| | | | Blunted affect, revoked group had significantly lower scores than the restored group (F = 17.44, p <.0001, d = 0.50) |
| | | | N.B. = "restored" = "succeeded = were legally restored to sanity" |

CR: Conditional Release; CD: Conditional Discharge; IAs: Insanity acquittees; ES: Effect size; GAF: General Assessment of Functioning.

## Appendix 6. Participant Information Sheet



[Vivienne Barnett,
School of Health & Social Sciences,
University of Edinburgh/ NHS Grampian
vivienne.barnett1@nhs.net]

# Participant Information Sheet

## The experiences of people living under Compulsion Order and Restriction Order (CORO) in Scotland.

**You are being invited to take part in a research study as your Clinical Care Team identified that you are eligible to participate. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.**

**What is the purpose of the study?**

The study aims to explore the experiences and the views of people who are living under Compulsion Order and Restrictions Orders (CORO) in Scotland. Interviews are designed to give a voice to people living under CORO.

**Why have I been asked to take part?**

You have been asked to take part as you have experience of living under a CORO.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep, and will have the opportunity to talk to the researcher about the study before you need to decide whether to take part. You will also be asked to sign a consent form.

If you decide to take part you are still free to change your mind at any time and can withdraw without giving a reason.

Please be assured that whether you choose to participate in this study or not or choose to withdraw from the study this will not affect the care you receive, or any decisions that are made about your CORO.

**What will I have to do?**

If you are interested and willing to take part in the study you will be asked to tell the clinician who approached you about this study who will contact Vivienne (the researcher in the study) to let her know you want to find out more about the study. Once Vivienne knows this, she will get in touch and will arrange a suitable time and place to meet. She will then talk through what would happen if you did decide to take part in the study and will ask you to sign a Consent Form to say that you have understood what the study would involve. You can then either complete the interview then, or else Vivienne will arrange another time to meet with you.

During the interviews Vivienne will ask you questions about your experience of life while being under a CORO. Questions are simple and open and you are free to decide what you would like to share.

**What will happen if I take part?**

The interview will last about 60 minutes. Interviews will be recorded on a digital recorder, so Vivienne can transcribe (type out) interviews. We hope that the interview will give you the opportunity to talk freely about your experiences of living under a CORO.

Vivienne may wish to meet with some participants again after the interview to check she has understood what they meant during the interview. However, this is not mandatory for participants to be able to take part in the initial interview. If you would not like to meet again after the interview to review your interview please do not initial the box corresponding to this in the consent form.

If you would like to be sent a summary of the research findings once the study is finished please let Vivienne know.

**What are the possible benefits of taking part?**

We hope that you feel this is a valuable area of research. The project provides the opportunity to share your experiences. This will help people who work with people who have COROs understand more about what this is like.

**What are the possible disadvantages and risks of taking part?**

Given the nature of the topic area, there is a possibility that some people may become upset. If this happens, the researcher will stop the interview, only continuing if the person feels able to do so. Please do seek support and discuss any concerns with your care team, alongside other support lines that might be of assistance.

In addition, there is a possibility that some people may disclose offending that they have not previously made their care team aware of or may disclose they are at risk of harm from other people or to themselves. It is also possible that some people may disclose that there are risks to other people. If that happened, Vivienne would follow standard procedures and relevant policies in NHS Grampian in reporting this information to the appropriate staff members to ensure everyone is kept safe. This will ensure that any issues are addressed appropriately.

Your clinical team will be informed if you disclose any risk to self, others and or previous offences they have not been made aware of. Thus, please be aware that any information of this nature you tell Vivienne during the interview may be shared with your clinical team thereafter. Vivienne will endeavour to be open with you about any information she may have a duty of care to pass on to your clinical team however depending on circumstances at interview this may or may not be made explicit at the time of interview.

Please be aware that you may contact the following services to discuss any distress related to the study:

- Your Clinical Team
- Breathing Space, call: 0800 83 85 87
  (is a free, confidential phone and web based service for people in Scotland experiencing low mood, depression or anxiety)
- Samaritans, call: 116 123
  (a free, confidential phone service open 24hours a day, 7 days a week to help when people are feeling down and distressed)

**What happens to the information when the study is finished?**

The digital audio recordings of the interviews will be deleted once transcribed (typed out) by the researcher. When the interviews are transcribed, any information that might identify who people are (e.g., names or places) will be removed. Consent Forms will be destroyed once the study is completed.

The transcripts of the interview, <u>on which all personally identifiable information is removed</u>, will be stored at Edinburgh University long-term secure storage depository. This will be held for a minimum of 3 years and then destroyed.

**Will my taking part in the study be kept confidential?**

All the information we collect during the course of the research will be kept confidential. The only exceptions would be if you tell Vivienne that you or another person is at risk of harm, about previous offences that you have not disclosed to your clinical team before or that you have concerns about the standard of care in NHS Grampian. If that happened, Vivienne would follow standard procedures and the relevant policies in NHS Grampian. This will ensure that any issues are addressed appropriately.

Your clinical team will be informed if you disclose any risk to self, others and or previous offences they have not been made aware of.

The research will use your exact words and the written transcript will remove any information that could personally identify you. Sections of the interview that cannot hide your identity will be excluded from the research. As part of the write up of the research, direct quotes from participants are sometimes used however none of these will be identifiable to individuals. Quotes will not be used if there is any risk that they may identify an individual.

**What will happen to the results of the study?**

The study will be written up as a thesis, for submission for a qualification: Doctorate in Clinical Psychology. The findings in the research could be communicated to a wider audience through professional publications, presentations and at conferences. However, it will not be possible for individual participants to be identified in these.

A summary of the research project will be sent to participants if they indicate at the time of the study that they would like to be sent this information when the study is finished.

**Who is organising the research and why?**

This study is being organised by the University of Edinburgh for a Doctorate in Clinical Psychology

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a research ethics committee. The North of Scotland (2) Research Ethics Committee has reviewed the study. NHS management approval has also been sought. The study is registered with the University of Edinburgh School of Health In Social Science Ethics Committee.

**How do I find out more?**

If you have any further questions about the study, please contact*:*

Vivienne Barnett

(Researcher)

E-mail: vivienne.barnett1@nhs.net

Phone: 01224 557 931 (Blair Unit, Psychology Secretary)

Or contact, the Academic Supervisor of this study:

Dr Suzanne O'Rourke
Lecturer/ Clinical Psychologist - School of Health in Social Science, University of Edinburgh
E-mail: Suzanne.O'Rourke@ed.ac.uk
Phone: +44(0) 131 650 4272

If you wish to speak to someone who is independent of the study please contact:

Dr Angus MacBeth

Lecturer/ Clinical Psychologist - School of Health in Social Science, University of Edinburgh

E-mail: angus.macbeth@ed.ac.uk
Phone: 0131 650 3893

If you wish to make a complaint about the study please contact The University of Edinburgh Research Governance:

E-mail: researchgovernance@ed.ac.uk

**How do I take part?**

Please contact the clinician who has offered you the opportunity to take part in this study. They will arrange a time and place for Vivienne to meet with you that is suitable for you.

Thank you very much for taking the time to read this information sheet.

**Data Protection**

*The University of Edinburgh is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Edinburgh will keep identifiable information about you for 3 months after the study has finished (Audio recordings will be deleted once transcribed. Consent forms will be destroyed within 3 months of the end of the study).*

*Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.*

*You can find out more about how we use your information by contacting:*

*Data Protection Officer contact information:*

*University of Edinburgh*

*Data Protection Officer*

*Governance and Strategic Planning*

*University of Edinburgh*

*Old College*

*Edinburgh*

*EH8 9YL*

*Tel: 0131 651 4114*

*dpo@ed.ac.uk*

*https://www.ed.ac.uk/records-management/privacy-notice-research*

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at https://www.ed.ac.uk/records-management/privacy-notice-research

If you wish to raise a complaint on how we have handled your personal data you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/

*NHS Grampian, NHS Forth Valley and NHS Lanarkshire will use your name, CORO status and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from University of Edinburgh and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS Grampian, NHS Forth Valley and NHS Lanarkshire will pass these details to University of Edinburgh along with the information collected from you. The only people in University of Edinburgh who will have access to information that identifies you will be people who need to contact you to interview you (for the study) or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.*

*NHS Grampian, NHS Forth Valley and NHS Lanarkshire will keep identifiable information about you from this study for 3 months after the study has finished (Audio recordings will be deleted once transcribed. Consent forms will be destroyed within 3 months of the end of the study).*

**Appendix 7. Participant Consent Form**

[Vivienne Barnett,
School of Health & Social Sciences,
University of Edinburgh/ NHS Grampian
vivienne.barnett1@nhs.net]

# CONSENT FORM

## The experiences of people living under Compulsion Order and Restriction Order (CORO) in Scotland.

**Participant ID:**

**Please initial box**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to consider the information and ask questions. This relates to Version 4/ 15-May-2019 of the information sheet that I have read. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. Any data gathered before I withdraw from the study will be retained and used in the study. ☐

3. I confirm that I consent to my Resident Medical Officer (RMO) (i.e. Consultant Psychiatrist) being sent written confirmation/notification that I am participating in this study. ☐

4. I confirm that should I lose capacity to consent during the course of the study I am willing for my data to be retained and used in the data analysis of the study. (If you do not initial this box then your data would be destroyed should you lose capacity to consent during the course of the study). ☐

5. I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsor (the University of Edinburgh) or from the/other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records. ☐

6. I agree to my interview being audio recorded. Only the researcher (Vivienne) and academic supervisor will have access to the audio recorded interviews and transcripts of interviews. The academic supervisor will not be able to tell who you are when they read the transcript as the documents will be given a different name (e.g. Interview 6). ☐

7. I give consent for the researcher to contact me after the initial interview to arrange to meet me again so I can check over my interview and the researcher can make sure they have understood what I meant during the interview. (You do not have to consent to this part in order to consent in the initial interview). Only initial this box if you would consent to meeting with the researcher again to review your interview. ☐

8. I consent to being sent a summary of the findings of this study and ☐

9. I consent to the need for disclosure should this be required. ☐

10. I agree to take part in the above study. ☐

| _____ | _____ | _____ |
|---|---|---|
| Name of Participant | Date | Signature |

| _____ | _____ | _____ |
|---|---|---|
| Name of Person taking consent | Date | Signature |

Original (x1) to be retained in site file. Copy (x1) to be retained by the participant.

## Appendix 8. Clinician Information Sheet

[Vivienne Barnett,
School of Health & Social Sciences,
University of Edinburgh/ NHS Grampian
vivienne.barnett1@nhs.net]

# The experiences of people living under Compulsion Order and Restriction Order (CORO) in Scotland.

**To: The Clinician**

My name is Vivienne Barnett and I am undertaking the Doctorate in Clinical Psychology at the University of Edinburgh. I am writing to tell you about a study that I would like to conduct for my DClinPsy thesis.

My project tries to better understand the experience and views of people who are living under Compulsion Oder and Restriction Order (CORO) in Scotland. Participants should be people who are currently living under a CORO and can be living in hospital or in the community (conditionally discharged).

There is a gap in research for professionals to understand the experiences of people who are under compulsory treatment, particularly COROs.

The study will consist of interviews with individuals, which will be digitally recorded and then transcribed. Questions are open-ended so that participants are in control of what they would like to share.

I have attached a Patient Information Sheet, which describes the study in more detail.

I hope to interview 10 to 12 people. The first 10 to 12 individuals who make it known to their clinician that they would like to take part in the study will be chosen for the interviews. Others might be contacted for interviews at a later stage in case any participants decide to drop out of the study.

**What will happen if my patient takes part?**

I would greatly appreciate if you would consider whether any of your patients who are currently under CORO would be able to take part. Please see the inclusion and exclusion criteria of the study below:

**Inclusion**

- Patients who are subject to CORO living in hospital or “conditionally discharged” CORO patients living in the community.

The rationale for including both subgroups is that given the small population of CORO patients, it would be prudent to include both groups in order to gather plentiful data. In addition, there may be interesting comparisons to be found between the two groups

and their experiences given that they will be at different places on their journey through the forensic estate and rehabilitating in the community. The study method - interpretative phenomenological analysis - is very suitable method for drawing upon rich narrative information and delineating comparative narratives between groups.

**Exclusion**

- Non-English speakers (as the method of data gathering is a semi-structured interview with and the nature of the study methodology – interpretative phenomenological analysis).
- Patients who are identified by clinicians as experiencing high levels of symptoms of mental illness or may be at risk of a high level of distress by participating in the interview.
- Patients where there would be concerns over capacity to consent to participation in the study.
- Patients who are identified by clinicians as not suitable for lone working due to potential risk to the researcher.

I would be grateful if you could offer eligible patients the opportunity to take part in the study and offer them a copy of the Patient Information Sheet to read.

If any patients express interest in taking part in the study I would then ask that you pass me on this information. I will then arrange a suitable time for me to meet with the patient to discuss the study and Patient Information and Consent Form further in order to ensure that they are aware of the requirements of the study. If they do wish to participate, I will complete a Consent Form with them and either conduct the interview at that point, or arrange this at a later date, depending on the preference of the individual.

**What are the potential risks for participants taking part in this study?**

Given the nature of the topic area, there is a possibility that some people may become upset. If this happens, I would stop the interview, only continuing if the person feels able to do so. The participant would then be encouraged to seek support and discuss any concerns with their Clinical Team. I would contact the patient's Clinical Team if the participant does become distressed, to inform them of the circumstances. Participants would be made aware of this process prior to participating.

In addition, there is a possibility that some people may disclose offending that was not previously known, or that they are at risk of harm from or to others or towards themselves. In such cases, appropriate Health and Social Work processes will be followed. Again, participants will be made aware of this prior to participating.

If any of your participants express a wish to participate in this study I would greatly appreciate if you could inform me of this and then I will arrange a suitable time and place to meet with them to explain the study and consent form further.

Yours sincerely,

Vivienne Barnett

(Researcher)

E-mail: vivienne.barnett1@nhs.net

Phone: 01224 557 931 (Blair Unit, Psychology Secretary)

Academic Supervisor of this study:

Dr Suzanne O'Rourke
Lecturer/ Clinical Psychologist - School of Health in Social Science, University of Edinburgh
E-mail: Suzanne.O'Rourke@ed.ac.uk
Phone: 0131 650 4272

If you wish to speak to someone who is independent of the study please contact:

Dr Angus MacBeth

Lecturer/ Clinical Psychologist - School of Health in Social Science, University of Edinburgh

E-mail: angus.macbeth@ed.ac.uk
Phone: 0131 650 3893

If you wish to make a complaint about the study please contact The University of Edinburgh Research Governance:

E-mail: researchgovernance@ed.ac.uk

## Appendix 9. Semi-structured Interview Schedule

# Semi-structured Interview Schedule

The interview schedule is developed to guide participants toward some key themes, while giving space for individual experiences and variations. The interview will consist of the following questions and possible prompts (P).

**Part One - General**

What's life like for you at the moment?

What kind of things do you do? (P)

How do you feel your life is going? (P)

**Part Two - CORO**

You're on a CORO, can you tell me what that means to you?

> *If the participant is not aware of what a CORO is or there is any confusion the interviewer will give the following explanation:*
>
> A CORO stands for a Compulsion Order and Restriction Order. It means that changes to your care plan have to be approved by the Scottish government/ministers (for example, for you to move to a different hospital or given periods of time outside of the hospital). It also means that you can only be discharged to the community by a Mental Health Tribunal. In the community, the Scottish Government would continue to be involved in approving the plans related to your care. (P)

Okay so you're on a CORO rather than a Compulsion Order or Compulsory Treatment Order, how do you think that affects things for you? (P)

Are there any differences? (?)

Can you tell me about how things were for you when you were first detained?

So when the CORO began, did that change things for you? (P)

**Part Three – Relationships and the Future**

How do you get on with staff?

How does being on CORO affect your relationships with staff? (P)

What is it like to be under the care of a mental health team? (P)

Can you tell me more about that? (P)

Can you tell me how being on CORO has impacted on your relationships with family and friends?

Can you tell me more about that? (P)

Has being on CORO impacted on developing new relationships and friendships? If so, how?

Can you tell me more about that? (P)

Where do you see your life going in the future?

Can you tell me more about that? (P)

## Appendix 10. Ethical Approval

**North of Scotland Research Ethics Service**
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558458
Facsimile: 01224 558609
Email: nosres@nhs.net

NHS Grampian

9 April 2019

Dr Suzanne O'Rourke
Doorway 6, Medical Quad
Teviot Place
EDINBURGH
EH8 9AG

Dear Dr O'Rourke

| | |
|---|---|
| **Study title:** | **The experiences of people living under Compulsion Order and Restriction Order (CORO) in Scotland.** |
| **REC reference:** | **19/NS/0015** |
| **Protocol number:** | **CAHSS1809/06** |
| **IRAS project ID:** | **249351** |

Thank you for your letter of 8 April 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Conditions of the favourable opinion**

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**Ethical review of research sites**

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

| *Document* | *Version* | *Date* |
|---|---|---|
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only): Clinical Trial Liability Insurance | | 31 July 2018 |
| GP/consultant information sheets or letters: Resident Medical Officer (RMO) | 2 | 14 January 2019 |
| Interview schedules or topic guides for participants: Semi-structured Interview Schedule | 2 | 14 January 2019 |
| IRAS Application Form: IRAS Form 14012019 | 249351/1287298/37/29 | 14 January 2019 |
| IRAS Checklist XML: Checklist 09042019 | | 9 April 2019 |
| Certificate of Employers' Liability Insurance - 01.08.2018 - 31.07.2019 | | 1 August 2018 |
| Public Liability Confirmation | | 24 July 2018 |
| Professional Indemnity Insurance | | 31 July 2018 |
| Initial Letter to NHS Forensic Service | 1 | 1 December 2018 |
| Introduction Letter to the Clinician | 1 | 1 December 2018 |
| Lone Working Risk Assessment | 1 | 14 May 2018 |
| Karen Allan CV | | 10 December 2018 |
| Initial Letter to NHS Forensic Service | 2 | 14 January 2019 |
| Introduction Letter to the Clinician | 2 | 14 January 2019 |
| GCP Certificate - Vivienne Barnett | | 10 January 2018 |
| Letter of Support for project from RMOs | | 21 January 2019 |
| Lone Working Risk Assessment | 2 | 21 January 2019 |
| Response to Provisional Opinion | | 18 March 2019 |
| Psychiatrist Letter - Response to Provisional Opinion | | 19 March 2019 |
| Response to Further Information Response not Complete Letter | | 8 April 2019 |
| Participant Consent Form | 4 | 8 April 2019 |
| Participant Information Sheet (PIS) | 3 | 24 January 2019 |
| Referee's report or other scientific critique report: Peer Review by Clinical Psychologist | | 22 January 2019 |
| Research protocol or project proposal | 2 | 14 January 2019 |
| Summary CV for Chief Investigator (CI): Suzanne O'Rourke | | 22 May 2018 |
| Summary CV for Student: Vivienne Barnett | | 16 November 2018 |
| Summary CV for Supervisor (student research): Suzanne O'Rourke | | 22 May 2018 |

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

**User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

**HRA Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities – see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

| | |
|---|---|
| **19/NS/0015** | **Please quote this number on all correspondence** |

With the Committee's best wishes for the success of this project.

Yours sincerely

**Professor Helen Galley**
**Chair**

Enclosures: "After ethical review – guidance for researchers" SL-AR2

Copy to: Ms Charlotte Smith

**Appendix 11. Study Protocol**

# Non-CTIMP Study Protocol

***The experiences of people living under Compulsion Order and Restriction Order (CORO) in Scotland.***

| | |
|---|---|
| | The University of Edinburgh<br>College of Arts, Humanities and Social Sciences<br>The University of Edinburgh<br>55 George Square<br>Edinburgh<br>EH8 9JU |
| Protocol authors | **Vivienne Barnett (Researcher/ Principal Investigator)** |
| Chief Investigator | **Dr Suzanne O'Rourke**<br>**Lecturer in Forensic Clinical Psychology**<br>**School of Health in Social Science**<br>**Clinical Psychology**<br>**University of Edinburgh** |
| Sponsor number | CAHSS1809/06 |
| REC Number | 19/NS/0015 |
| | |
| Version Number and Date | **Version 2 - 14-Jan-2019** |

# LIST OF ABBREVIATIONS

| | |
|---|---|
| **ACCORD** | Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board |
| **AE** | Adverse Event |
| **AR** | Adverse Reaction |
| **CI** | Chief Investigator |
| **CRF** | Case Report Form |
| **GCP** | Good Clinical Practice |
| **ICH** | International Conference on Harmonisation |
| **PI** | Principal Investigator |
| **QA** | Quality Assurance |
| **REC** | Research Ethics Committee |
| **SAE** | Serious Adverse Event |
| **SAR** | Serious Adverse Reaction |
| **SOP** | Standard Operating Procedure |
| **CORO** | Compulsion Order & Restriction Order |
| **IPA** | Interpretative Phenomenological Analysis |

# INTRODUCTION

## BACKGROUND

### Compulsory treatment and mental health reform in Scotland

Compulsory treatment for mental health difficulties can be defined as legally imposed medical or psychosocial treatment in hospital or in the community. In Scotland, any person subject to compulsory treatment under civil powers of the Mental Health (Care & Treatment) (Scotland) Act 2003 (MHCT Act) will, by definition, have or be likely to have, impaired ability to make decisions about medical treatment. Therefore, in this case, the person's capacity to consent cannot be presumed. If the person is being treated under powers for mentally disordered offenders, the test for decision-making ability does not apply (Mental Welfare Commission, 2011).

In 2001, the Mental Health (Scotland) Act 1984 was reviewed by a government committee led by Rt. Hon. Bruce Millan as the initial step in the overhaul of mental health services in Scotland (Scottish Executive, 2001). The committee produced a report ("Millan Report") outlining the principles on which new mental health services should be based: non- discrimination, equality, respect for diversity, reciprocity, informal care, participation, respect for carers, least restrictive alternative, and benefit. The review focused on increasing community-based care and use of informal care where possible. The new mental health legislation which resulted from the report, the MHCT Act provides the legal backbone for forensic inpatient and community care.

The MHCT Act introduced new roles and provisions including Community Treatment Orders (CTOs) and amended the Criminal Procedures (Scotland) Act (1995) to allow similar orders, Compulsion Orders. Both of these orders allow an individual to be returned to the community under several conditions which may include: where they live; the professionals they must allow to visit them at their home; and the treatment they must receive. This renewed suite of legislation was designed to increase service user participation, ensure treatment was beneficial and was the 'least restrictive' alternative: aiming to reduce concerns regarding the ethics of compulsion. Professionals have argued that the new Act and its principles have brought about a paradigm shift in the culture of detention, subjecting the decision to greater scrutiny (Scottish Government Social Research [SGSR], 2009). However, critics argue that compulsory treatment for mental health difficulties is paternalistic, discriminatory, likely to escalate levels of coercion used in psychiatry, further reduce freedom of choice for people with mental illness (Lawton-Smith, Dawson, & Burns, 2008) and appears to violate the UN Convention on the Rights of Persons with Disabilities (Szmukler, Daw, & Callard, 2014).

### Compulsion Order and Restriction Order (CORO)

Where there is an ongoing risk of serious harm to others the Court may make a Restriction Order in addition to a Compulsion Order which serves the purpose of protection of the public. A patient on a CORO can only be transferred to another hospital or given periods of time outside hospital with the permission of the Scottish Ministers. Where a patient is subject to a CORO they can only be discharged to the community by a Mental Health Tribunal. Usually strict conditions will be placed on a patient on CORO in the community and the Scottish Government closely monitors the management of these patients. While a patient is on a CORO, either in hospital or conditionally discharged to the community, they are a "restricted patient" (The Scottish Government, 2012).

There are approximately 290 restricted patients in the Scottish system at any one time. Just over half are detained in the State Hospital with the remainder detained in local psychiatric hospitals or living in the community on conditional discharge (The Scottish Government, 2018).

### Experiences of Compulsory Treatment

Compulsory treatment orders are present in most advanced mental health systems however there is a dearth of evidence in terms of compulsion in forensic populations. At the time of writing only two studies (using the same sample) exploring the experiences of patients under the MHCT Act in Scotland are available (SGSR, 2009; Ridley & Hunter, 2013). The studies conducted interviews with patients under various orders over the first 2-3years of implementation of the Act. Both studies included patients from the State Hospital, one refers to a patient who stated "I'm on a restriction order" (SGSR, 2009) and that 10% of service users interviewed were on "Specialist Order, Criminal Justice" but this is not delineated further into specific orders. Thus, it is not possible to identify any findings specific to patients under CORO.

A non-peer-reviewed cohort study conducted by the Scottish Government used an undisclosed qualitative approach "using interviews and focus groups…to articulate different viewpoints and explore individual experiences of compulsion" (SGSR, 2009).It was commissioned by the Scottish Government Health Directorate to evaluate the implementation of the MHCT Act by exploring experiences and perceptions of all stakeholders. "Key emergent themes" identified were: compulsory care and treatment is inherently unwelcome; care and treatment regimens

tended to be based on the medical model with alternative psychosocial treatment infrequently offered; service users did not feel as involved as they could be in decision-making; there were gaps in the range of community resources available; concerns that the Act had created a two-tier mental health service: one for the few under compulsory measures and the other for everyone else with mental health problems. The methodology of this study appears unclear and standard qualitative methods such as interpretative phenomenological analysis or grounded theory were not used. It is not possible to identify how widespread or endorsed particular “themes” were.

The second study found that the new legislation had a limited impact on participation in the process of compulsion (Ridley & Hunter, 2013). Consensus was that although service users felt there was increased opportunity for their voices to be heard, this was not matched by having increased influence over professional decision-making, especially in relation to drug treatments. According to people's direct experiences, the passing of the legislation in itself had done little to change the dominant psychiatric paradigm. While providing a foundation for improving the process of compulsion, the findings suggest that as well as legislative reform, fundamental shifts in practice are needed both in terms of the nature of therapeutic relationships, and in embracing more holistic and recovery perspectives.

Literature from other countries which use similar forms of mental health legislation have generated mixed findings. A review of five (Swedish & UK) qualitative studies exploring patients’ experiences of involuntary admission and treatment found the main areas of significance: patients’ perceived autonomy and participation in decisions for themselves, their feeling of whether or not they are being cared for and their sense of identity (Katsakou & Preibe, 2007).

## RATIONALE FOR STUDY

Overall, there is evidence of the effects of compulsory treatment on individuals. Only a single sample of people under compulsion of the MHCT-Act in Scotland have been the focus of research (Ridley & Hunter, 2013; SGRS, 2009). No methodologically sound research exists specifically into people living under CORO. As CORO is more restrictive than standard compulsory treatment it is important to examine what additional effects CORO may have on individuals. A general theme throughout previous findings on compulsion is that perception of negative experiences are tempered by perception of relationships with professionals as supportive (Gault, 2009; Gibbs et al., 2005; Ridley & Hunter, 2013; Tan et al., 2010). Although, evidence points towards a moderating effect of relationships relating to the impact of compulsion the added complexity/restriction of CORO requires exploratory research to examine global effects on the individual.

The proposed study would ask how patients experience life under the Compulsion Order and Restriction Order (CORO) legislation in Scotland by way of semi-structured interview. The study offers no clear benefit for participants. Though, CORO patients currently have limited formal, confidential avenues upon which to advocate their experiences publicly, so this research may provide an avenue for participants to make their views known. Previous studies have found that participation in qualitative research interviews to have therapeutic benefit to participants (Corbin & Morse, 2003; Murray, 2003). Corbin & Morse (2003) concluded that qualitative research using interviews poses no greater risk than everyday life. The study may benefit forensic mental health services in Scotland by providing feedback from patients regarding the positives and difficulties people live under CORO face and how services can best support them.

## STUDY OBJECTIVES

## OBJECTIVES

### Primary Objective

The primary objective/ research question is:

How do patients experience life under the Compulsion Order and Restriction Order (CORO) legislation in Scotland?

## ENDPOINTS

### Primary Endpoint

Detail primary endpoint(s)

The primary endpoint will be themes which are generate from the analysis of data transcribed from interviews with participants. Themes will be generated from interpretative phenomenological analysis.

## STUDY DESIGN

### Design

An exploratory, qualitative design will be utilised to understand the personal lived experience of individuals living under CORO in Scotland. The research will consider how they make sense of their subjective experience and the meaning attached to events which will be examined using Interpretative Phenomenological Analysis (IPA). Data collection will be through semi-structured interviews to access rich and detailed personal accounts.

### Procedure

Clinicians of CORO patients in NHS health boards (the Forensic Mental Health Multi-disciplinary team) will be informed about the current study. The researcher will then offer to present the study at team meetings and/or information sheet regarding the project will be emailed to all clinicians in the service. All clinicians (including Psychiatrists, Clinical Psychologists, Occupational Therapists and Psychiatric Nurses) will be asked to use their professional expertise in considering whether a patient will manage the potential emotional demands of the interview and has the capacity to consent to interview. Once a list of patients eligible to be approached has been made, Clinicians in the service will approach the potential participants with an information sheet regarding the study. Patients will be approached by no more than one clinician to take part in the study. If the patient then states that they wish to participate in the study the Clinician will arrange a time for the participant and researcher to meet (see Lone Working Risk Assessment). The interview will take place at a health and social care setting which is deemed suitable and safe by the patient Care Team (e.g. Low Secure Unit Interview Room).

The Information Sheet will be reviewed with the participant by the researcher, to ensure that the potential participant fully comprehends the study and also their right to withdraw at any time (and that any data gathered before they withdraw will be kept anonymously and used in analysis). Participants who are met face-to-face will be asked to sign the Consent Form.

Written consent to participate in the study will be obtained at the arranged interview time prior to beginning the interview. This will include the explanation that they have a right to withdraw without giving a reason at any point of the study and that information gathered before this point would be used in the study. The researcher will also offer the participants for the interview to take place more than 24 hours after written consent has been taken and a further date and time to meet to conduct the interview would then be arranged. Participants will have the option to consent or not to taking part in participant validation (i.e. actively involving the research participant in checking and confirming the researcher's interpretations of their interview) on one occasion in the months after the interview. To take part in the data collection part of the study participants do not have to consent to this option: they are able to participate in the interview only and no further contact with the researcher thereafter.

Patients who provide written consent to participate will be asked to complete an interview between 30-60 minutes in length. Sixty minutes would be the upper limit in order to ensure that demands upon patients are not excessive. At the start of the interview patients will be offered a planned "comfort break" and made aware that they are able to take a break at any point during the interview as and when they feel necessary.

Semi-structured interviews will be conducted (using an interview schedule) which explore the personal experience of patients subject to CORO. This will consider the impact of CORO on their: mental health; quality of life; relationships with professionals, family, friends; and occupational opportunities.

Interviews will be audio recorded for the purpose of interview transcription and data analysis. Data transcripts will be anonymized prior to analysis. Data will be securely stored in line with University of Edinburgh and NHS Grampian procedures.

### Analysis

IPA will be used as a methodology for data gathering and analysis as the current study seeks to gather rich, detailed data to explore the lived experiences of individuals living under CORO. As the current study aims to explore patient experience of life under CORO, a very complex phenomenon on which limited literature exists, a qualitative method was thought to be the most suited to address the research question. The researcher will consider how sense is made of their experience at an individual level.

Transcripts will undergo investigator triangulation (e.g. co-investigators reviewing sub-samples of transcripts for coding and themes) (Denzin, 1978) and participant validation (e.g. actively involving the research participant in checking and confirming the researcher's interpretations of their interview) (Doyle, 2007). This would aim to mitigate the inherent potential for researcher bias in qualitative research given that often the researcher is data collector and data analyst (Miles and Huberman, 1994).

**Additional Information**

Demographic information (i.e. gender and age) will be gathered from the patients being interviewed.

## STUDY POPULATION

## NUMBER OF PARTICIPANTS

**Study Population**

Participants will be patients who are subject to CORO under the care of NHS Grampian Forensic Mental Health Service (in the first instance). A convenience sample will be recruited in order for data collection to meet the demands of the thesis project whilst accessing the lived experienced of the individuals in this unique group.

A sample size of approximately ten to twelve participants will be sought.

If an adequate number of participants (ten to twelve) cannot be sought within NHS Grampian then permission to recruit participants from other health board areas will be sought. This study is currently being proposed as a single-centre study and thus if data collection in further health boards is required an amendment would be sought in future,

## INCLUSION CRITERIA

Inclusion

- Patients who are subject to CORO living in hospital or "conditionally discharged" patients living in the community.

The rationale for including both subgroups is that there may be interesting similarities and contrasts to be found between the two groups and their experiences given that they will be at different places on their journey through the forensic estate and rehabilitating in the community. IPA is very suitable method for drawing upon rich narrative information and delineating comparative narratives between individuals.

## EXCLUSION CRITERIA

Exclusion

- Non-English speakers due to nature of study methodology (i.e. IPA).
- Patients who are identified by clinicians as experiencing high levels of symptoms of mental illness.
- Patients who are identified by clinicians to be at risk of a high level of distress by participating in the interview.
- Patients where there would be concerns over their capacity to provide informed consent to participation in the study.
- Patients who are identified by clinicians as not suitable for lone working due to potential risk to the researcher.

## PARTICIPANT SELECTION AND ENROLMENT

## IDENTIFYING PARTICIPANTS

Clinicians of CORO patients in NHS health boards (the Forensic Mental Health Multi-disciplinary team) will be informed about the current study. These members of the potential participants care team will have access to medical records to check whether potential participants meet inclusion criteria. The researcher will not have access to potential participants medical records.

The researcher will then offer to present the study at team meetings and/or information sheet regarding the project will be emailed to all clinicians in the service. All clinicians (including Psychiatrists, Clinical Psychologists, Occupational Therapists and Psychiatric Nurses) will be asked to use their professional expertise in considering whether a patient will manage the potential emotional demands of the interview and has the capacity to consent to interview. Once a list of patients eligible to be approached has been made, Clinicians in the service will approach the potential participants with an information sheet regarding the study. Patients will be approached by no more than one clinician to take part in the study. If the patient then states that they wish to participate in the study the Clinician will arrange a time for the participant and researcher to meet.

### CONSENTING PARTICIPANTS

Informed consent will be obtained from the research participants.

The Information Sheet will be reviewed with the participant in person with the researcher, to ensure that they fully comprehend the study and also their right to withdraw at any time (and that any data gathered before they withdraw will be kept anonymously).

If the participant wishes to take part in the study they will be asked to sign the Consent Form if they consent. Consent will be obtained from the patient to participate in both data collection and the likely outcomes of data analysis and dissemination by the researcher in person.

Participants will be offered the opportunity to then take part in the interview directly after consent has been taken or to meet more than 24 hours later for the interview. The interview will then take place at a health and social care setting which is deemed suitable and safe by the patient Care Team (e.g. Low Secure Unit Interview Room).

If the interview is on a different date to initial consent taking then consent will be reconfirmed immediately prior to the interview. If the participant no longer consents they will be withdrawn from the study.

## Withdrawal of Study Participants

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form, if possible. The participant will have the option of withdrawal from

(i) all aspects of the trial but continued use of data collected up to that point

(ii) all aspects of the trial with removal of all previously collected data.

(iii) all aspects of the trial with removal of previously collected and stored participant samples.

The participant will not be required to give any reason for their withdrawal. The Chief Investigator or Investigators may withdraw participants from the study at any point if they perceive participation as no longer in the best interests of the participant, for example, if they appear unduly anxious or distressed, or presenting a threat (e.g. during interview).

Participant distress is considered unlikely to occur during the interview.

## STUDY ASSESSMENTS

The study procedure will consist of one semi-structured interview lasting between 30-60 minutes. This interview will be administered by the Principal Investigator and conform to the Interview Schedule.

Participants will be offered the option to take part in participant validation of the themes and interpretations taken from their interview in the months after the interview. It is not mandatory for participants to take part in this and they can make their intentions clear at time of consent taking/on the consent form.

## DATA COLLECTION

The research interview will be conducted by the Principal Investigator and recorded on an NHS encrypted audio recording device. This will allow the researcher/Principal Investigator to listen back to the interview after and transcribe it. The audio file will be deleted from the recording device when the study is finished. Each transcript will be given a pseudo-anonymous title e.g. Interview 7.

Only the Principal Investigator will have access to the participants audio recorded data during the study. The written transcripts of the interviewers will be analysed by the Principal Investigator, Chief Investigator and the Academic Supervisor.

## STATISTICS AND DATA ANALYSIS

## SAMPLE SIZE CALCULATION

The study will aim to recruit 10-12 however will aim to over-recruit in anticipation of attrition. This will allow the researcher to focus on the quality rather than quantity of the data and ensure adequate time is given to detailed analysis and reflection within the time constraints of the study. A sample size of between 4-10 interviews for professional doctorates is advised (Smith et al., 2009). This ensures that the research is true to the idiographic rather than nomothetic nature of IPA as large datasets may impede successful analysis. The recruitment of 10-12 participants for the current study aims to represent multiple perspectives on the phenomena under study while maintaining detailed analysis.

As of the 2013 Forensic Mental Health Census of Scotland there were 182 people living under CORO in Scotland. Therefore, a sample of 10-12 of these individuals (around 6% of the overall population) appears realistic as this is a multi-centre study with potential access to all health boards (thus all CORO patients) in Scotland.

## PROPOSED ANALYSES

Interpretative Phenomenological Analysis will be used as a methodology for data gathering and analysis as the current study seeks to gather rich, detailed data to explore the lived experiences of individuals living under CORO. As the current study aims to explore patient experience of life under CORO, a very complex phenomenon on which limited literature exists, a qualitative method was thought to be the most suited to address the research question. The researcher will consider how sense is made of their experience at an individual level.

Interviews will be transcribed verbatim and anonymised for data analysis. IPA will be used to enable an exploratory, open approach to the way in which participants make sense of their personal lived experience (Smith et al., 2009). In addition, the researcher will make note of their reflections on interviews to create context to interviews and consider any relevant information that is not captured by the interview recordings.

Analysis will follow the steps suggested by Smith, Flowers and Larkin (2009). The researcher will work intensively with the transcriptions, annotating them closely ('coding') for insights into the participants' experience and perspective on their world. The researcher will then catalogue the emerging codes and look for patterns (“themes”) in the codes. Themes are recurring patterns of meaning (ideas, thoughts, feelings) throughout the text. Themes are likely to identify both something that *matters* to the participants (i.e. an object of concern, topic of importance) and convey something of the *meaning* of that thing. Some themes will eventually be grouped under much broader themes called 'superordinate themes' and ‘sub-themes’ within these. The final set of themes will be summarised and placed into a table where evidence from the text will be given to substantiate the themes produced by a quote from the text.

Transcripts will undergo investigator triangulation (e.g. co-investigators reviewing sub-samples of transcripts for coding and themes) (Denzin, 1978) and participant validation (e.g. actively involving the research participant in checking and confirming the researcher’s interpretations of their interview) (Doyle, 2007). This would aim to mitigate the inherent potential for researcher bias in qualitative research given that often the researcher is data collector and data analyst (Miles and Huberman, 1994).

## ADVERSE EVENTS

A log of AE and SAEs will not be kept as the study is non-interventional and will for most participants be a one off meeting (a small number of participants may meet the interview again for participant validation of their interview).

OR

Serious Adverse Events may occur to participants during the research but which are not related to the research itself (e.g. accidental injury occurring to participant during the interview (fall off their chair)).

A log of any SAEs (e.g. accidental injuries) which occur to participants during the research will be kept and the Principal Investigator and/or Chief Investigator will contact the sponsor to notify them of any SAEs which may occur. Researcher/Interviewer will contact relevant person (e.g. Ward Manager) to ensure any first aid requirements of the participant are attended to.

## OVERSIGHT ARRANGEMENTS

## INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation

## STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

## GOOD CLINICAL PRACTICE

## ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

## INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

Delegated tasks must be documented on a Delegation Log and signed by all those named on the list prior to undertaking applicable study-related procedures.

## Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor(s).

The Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Investigator Site File (ISF) and participant's medical notes (if applicable).

## Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

## Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

## Investigator Documentation

- The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

## GCP Training

For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory requirement unless deemed so by the sponsor. GCP training status for all investigators should be indicated in their respective CVs.

## Confidentiality

All reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

## Data Protection

All Investigators and study site staff involved with this study must comply with the requirements of the Data Protection Act 2018 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Access to collated participant data will be restricted to individuals from the research team treating the participants, representatives of the sponsor(s) and representatives of regulatory authorities.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

## STUDY CONDUCT RESPONSIBILITIES

## PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

## MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

## SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

## STUDY RECORD RETENTION

Audio recordings will be deleted once transcribed. Consent forms will be destroyed within 3 months of the end of the study.

When the study has ended the transcripts of interviews will be stored on the University of Edinburgh Long Term data storage depository for a minimum of 3 years. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

## END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

## INSURANCE AND INDEMNITY

The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.
- Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

## REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

## AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.